



June 30, 2021

Emma Lewis
American Oversight
1030 15th Street NW, B255
Washington, DC 20005

RE: FDA FOIA Request 2020-2523;
American Oversight v. HHS et al., Civil No. 20-cv-01063

Dear Ms. Lewis:

This is in response to the Freedom of Information Act (FOIA) request numbers 2020-2523 that is the subject of the Amended Complaint filed in *American Oversight v. HHS et al.*, Civil No. 20-cv-01063, now pending in the U.S. District Court for the District of Columbia.

FDA's Office of the Commissioner sent records to the Department of Health and Human Services and the White House for further review and return to us. That consultation has been completed for some records. Those records, identified as FDA-OC-2020-2523-000484 through FDA-OC-2020-2523-000774 are enclosed.

We have withheld portions of these pages under the exemptions provided in 5 U.S.C. §§ 522(b)(4), (b)(5), and (b)(6) of FOIA, as delineated below:

Exemption (b)(4) permits the withholding of trade secrets and /or commercial or financial information that was obtained from a person and that is privileged or confidential.

Exemption (b)(5) permits the withholding of inter-agency or intra-agency memoranda or letters that would not be available by law to a party other than an agency in litigation with the agency. This exemption includes communications records which are part of the deliberative process and pre-decisional. Disclosure of such material could inhibit the open and candid expression of opinions and diminish the quality of the decision-making process.

Exemption (b)(6) permits the withholding of information which, if released, would constitute a clearly unwarranted invasion of personal privacy. The information that has been withheld under Exemption (b)(6) consists of personal information, such as direct contact information, and conference and passcode numbers. In this case, it was determined that there is no countervailing public interest qualifying under the standard set forth under exemption (b)(6) to release the personal identifying information of certain third parties.

Please direct any questions regarding this response to Amy Powell of the U.S. Department of Justice, at (919) 856-4013 or Amy.Powell@usdoj.gov.

Sincerely,

Meredith J. Schlaifer -S

Digitally signed by Meredith J.

Schlaifer -S

Date: 2021.06.30 09:54:20 -04'00'

Meredith J. Schlaifer, M.S., J.D.

FOIA Officer, Office of the Commissioner

Division of Freedom of Information

U.S. Food and Drug Administration

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/31/2020 7:29:11 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: Rural Testing

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Date: March 30, 2020 at 3:56:26 PM EDT
To: Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
Cc: Monroe, Stephan S (CDC) <stm2@cdc.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>, Schuchat, Anne (CDC) <acs1@cdc.gov>, Haddad, Carla (OS) <Carla.Haddad@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Haddad, Carla (OS) <Carla.Haddad@hhs.gov>
Subject: RE: Rural Testing

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/30/2020 3:58:51 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
Subject: Fwd: Rural Testing

Thoughts?

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Date: March 30, 2020 at 3:56:26 PM EDT
To: Jernigan, Daniel B (CDC) <dbj0@cdc.gov>
Cc: Monroe, Stephan S (CDC) <stm2@cdc.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>, Schuchat, Anne (CDC) <acs1@cdc.gov>, Haddad, Carla (OS) <Carla.Haddad@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Haddad, Carla (OS) <Carla.Haddad@hhs.gov>
Subject: RE: Rural Testing

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/31/2020 7:48:38 AM
To: Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: [EXTERNAL] Abbott COVID-19 update

From: Wainer, Andrea F <andrea.wainer@abbott.com>
Date: March 31, 2020 at 1:22:02 AM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Ford, Robert B <Robert.Ford@abbott.com>
Subject: RE: [EXTERNAL] Abbott COVID-19 update

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/15/2020 5:55:18 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Issue for VP TF

(b) (5)

Steve

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 14, 2020 at 1:58:13 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Issue for VP TF

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/9/2020 5:36:10 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Subject: Tentative: ALS Check-In
Location: Dial-in 202-395-6392 (b) (6)
Start: 4/9/2020 5:45:00 PM
End: 4/9/2020 6:15:00 PM

Recurrence: (none)

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/13/2020 8:39:19 AM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: list of essential tests and items from China

Ok thx

Sent from my iPhone

On Apr 13, 2020, at 8:36 AM, Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov> wrote:

Individual items

Sent from my iPhone

On Apr 13, 2020, at 8:24 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Joe,
Thank you. [REDACTED] (b) (5) Keagan, let's talk.
Steve

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: April 13, 2020 at 8:23:50 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: list of essential tests and items from China

[REDACTED] (b) (5) Jared is going to trouble shoot.

From: Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]
Sent: 3/26/2020 7:30:35 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (5) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rutter, Joni L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a90497bad684a6b81166a82a65e76c3-HHS-joni.ru]; Brooks, John T (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=def0cf9cf9f84fc6a40c4dde8c51b199-HHS-zud4-cd]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Hunter, Nina L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8005f93bd66a4dfc83ebdaa67d9fd33b-NLH]
Subject: Re: Collection of COVID-19 patient data from medical records

Thank you very much, Steve.

Right now I am working with Joni Rutter at NIH/NCATS and John Brooks at CDC. (b) (5)

I really appreciate all of your input.

Amy

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Thursday, March 26, 2020 5:39 PM
To: Fauci, Anthony S (NIH) <(b) (6)@niaid.nih.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Debi Birx <Deborah.L.Birx@nsc.eop.gov>
Cc: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Collection of COVID-19 patient data from medical records

Tony, Bob and Debi,
Amy is working on a (b) (5)

I am copying Amy to see if she has anything else to add. (b) (5).

Thanks
Steve

From: Mail Delivery System [MAILER-DAEMON@fda-ifw-00.fda.gov]
Sent: 3/22/2020 8:43:26 PM
To: mitchellkatz@nychhc.org
Subject: Undeliverable: [EXTERNAL] re ramping up personnel and ventilators
Attachments: Re: [EXTERNAL] re ramping up personnel and ventilators

Your message

To: Birx, Deborah L. EOP/NSC; mitchellkatz@NYCHHC.org
CC: Mary Dale Peterson
Subject: Re: [EXTERNAL] re ramping up personnel and ventilators
Sent: 3/22/2020 8:43:23 PM

The following message to <mitchellkatz@nychhc.org> was undeliverable.
The reason for the problem:
5.1.1.0 - Unknown address error 550-'#5.1.0 Address rejected.'

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/31/2020 1:35:01 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: Confidential Draft Press Release
Attachments: Confidential Draft Release.docx

FYI

From: Daniel O'Day <daniel.oday@gilead.com>
Date: March 31, 2020 at 1:34:12 PM EDT
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Brett Pletcher <Brett.Pletcher@gilead.com>
Subject: Confidential Draft Press Release

Dear Janet and Steve,

Janet, as mentioned briefly yesterday, I am writing to share with you a draft announcement we would like to issue later this week, which at a high level commits to donating [REDACTED] (b) (4) of remdesivir at no cost. As public and government interest increases daily, and concerns about cost during the peak of this pandemic are top of mind, I feel a responsibility to communicate this commitment even ahead of clinical data or a regulatory authorization of any kind. At the same time, because existing supply is limited, we also want to communicate our expansive efforts to increase supply as rapidly as possible, through our own efforts and partnerships with external pharmaceutical and chemical manufacturing companies. This is critical to assuring a coordinated effort across the globe that can maximize the production of remdesivir if needed, and is time sensitive.

The point of this communication is to assure the public of our view – that this is an extraordinary time and we will take extraordinary measures to ensure access to remdesivir, through current expanded access programs, and through other mechanisms when and if data supports broader access. This is also a follow-on to my open letter this past weekend on the Gilead website about our Compassionate use and Expanded access efforts, and consistent with our commitment to transparency.

We are sharing this draft press release in parallel with the review team at FDA, following the process my regulatory team follows for standard submissions and discussion. I appreciate you helping us to keep this information confidential, and also appreciate you letting me know your thoughts by the end of the day if possible.

We would also intend to share this with members of the Coronavirus task force, and the white house as a second step tomorrow prior to release.

Please call or email at any time. Cell: [REDACTED] (b) (6)

Best,
Dan

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b) (6) STEPHEN.HAH]
Sent: 3/30/2020 12:01:51 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Updated CTAP Graphic
Attachments: CTAP_print_combined_v4_3.30.20.pdf

We're putting it in landscape version but wanted you to see most recent version.
Steve

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: March 30, 2020 at 11:55:11 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: Updated CTAP Graphic

Dr. Hahn, please see an updated graphic attached. The following changes have been made:

- Data points have been added for the projected number of doses available for convalescent plasma and hyperimmune globulin.
- [REDACTED] (b) (5)
- [REDACTED]
- IL-6 Inhibitors are shown to have "Trials Ongoing" in April (since trials for one therapy are starting this month).
- The status of clinical trials/production of hyperimmune globulin now reads, "Working with manufacturers and on donor identification to ramp up production."

We'll have a formatted one-pager describing CTAP to you shortly.

--

Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/1/2020 12:34:13 PM
To: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Joe Grogan (Joseph.J.Grogan@who.eop.gov) [Joseph.J.Grogan@who.eop.gov]
Subject: Re: Slides for noon teleconference

Thx

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Date: April 1, 2020 at 12:31:48 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Joe Grogan (Joseph.J.Grogan@who.eop.gov) <Joseph.J.Grogan@who.eop.gov>
Subject: FW: Slides for noon teleconference

Frank

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Sent: Wednesday, April 1, 2020 11:47 AM
To: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: Fwd: Slides for noon teleconference

Here are slides from Dan O'Day for Gilead call. Would you mind adding to the invite so all folks can access

From: Daniel O'Day <daniel.oday@gilead.com>
Date: April 1, 2020 at 11:37:42 AM EDT
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Slides for noon teleconference

Hi Colin,

Can you please distribute to the participants from the USG side for our noon call.

Best,
Dan

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/30/2020 7:54:20 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Need the CTAP graphics for my call with Joe Grogan at 7:45
Attachments: CTAP_print_3.29.20.pdf

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: March 30, 2020 at 7:09:38 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Need the CTAP graphics for my call with Joe Grogan at 7:45

Apologies for the delay – here is the current draft. Please let us know if you have any comments or edits. (b) (5)

[REDACTED]

--

Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, March 30, 2020 7:05 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Need the CTAP graphics for my call with Joe Grogan at 7:45

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/30/2020 7:27:46 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Need the CTAP graphics for my call with Joe Grogan at 7:45
Attachments: CTAP_print_3.29.20.pdf

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: March 30, 2020 at 7:09:38 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Need the CTAP graphics for my call with Joe Grogan at 7:45

Apologies for the delay – here is the current draft. Please let us know if you have any comments or edits. (b) (5)

[REDACTED]

--

Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, March 30, 2020 7:05 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Need the CTAP graphics for my call with Joe Grogan at 7:45

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/31/2020 6:12:53 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
Subject: Two issues

Debi,

Sorry to bother you. There are two issues that require some urgent advice/follow up

1. Request from Gilead to discuss remdesivir
2. Serology update

If you have 5 minutes to talk tomorrow, please let me know.

Thanks

Steve

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/31/2020 7:54:26 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]

We're obviously going to miss our 7:45 call. Want to catch you up on CTAP roll out, convalescent plasma, hyperimmune globulin, and supply chain issues. Let me know what works for you.

Thanks

S

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/24/2020 6:30:58 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Summary of clinician feedback
Attachments: Rapid Clinician impressions from Oracle COVID 032320docx.docx

Clinician feedback on the Oracle system

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Date: March 24, 2020 at 9:30:07 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: Summary of clinician feedback

Hi - As per our discussion this morning, here is a quick summary of the feedback from 30 clinicians who used the Oracle COVID-19 system yesterday.

Take care,

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: 240-429-7034
Email: amy.abernethy@fda.hhs.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/31/2020 12:35:17 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Please send to me
Attachments: UPDATED_CTAP_print_combined_V8_3.30.20.pdf; CTAP-handout-1col-draft3.pdf

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: March 31, 2020 at 12:06:13 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Please send to me

If it's not too late

(b) (5)

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Guram, Jeet
Sent: Tuesday, March 31, 2020 11:14 AM
To: 'Hahn, Stephen' <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Please send to me

Here is the latest version of the graphic, and I've re-attached the bullets page as well.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 11:05 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Please send to me

Ok thx

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: March 31, 2020 at 10:29:25 AM EDT

To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Please send to me

Got it, [REDACTED] (b) (5)
[REDACTED] I'll send the version of the graphic with the larger font size as soon as it comes in, which should be later this morning.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 10:25 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Please send to me

[REDACTED] (b) (5)

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: March 31, 2020 at 9:50:15 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Please send to me

(b) (5)

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Guram, Jeet
Sent: Tuesday, March 31, 2020 9:17 AM
To: 'Hahn, Stephen' <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Please send to me

Here are the documents – the team is working on making the font larger for the graphics document, I'll check on the status of that.

(b) (5)

--

Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 9:03 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Please send to me

The 3 pager CTAP document
Page 1 the bullet points about the program
Pages 2-3 graphics of pipeline

The Secretary wants this (b) (5) When can you
get this to me?
Thanks
Steve

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/24/2020 5:40:14 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: FW: Gilead FDA material
Attachments: protocol GS-US-540-5821_Aproved.pdf; CU Update for FDA_final.pptx

Need to talk to you about this.
S

From: Daniel O'Day <daniel.oday@gilead.com>
Date: March 23, 2020 at 3:48:06 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Subject: FW: Gilead FDA material

Dear Deborah and Steve,

Steve, I thought I would share the attached with Deborah as well, as we have not had a chance to connect yet today, and I know how busy you both are! (and should we connect I wanted Deborah to have the material in front of her) I know Steve's team at FDA and our Clinical team discussed the protocol (first attachment) and are well on the way to implementation.

The bigger issue is the [REDACTED] (b) (4)
[REDACTED]
[REDACTED]

Best,
Dan

From: Daniel O'Day <daniel.oday@gilead.com>
Date: Sunday, March 22, 2020 at 10:37 PM
To: "sh1@fda.hhs.gov" <sh1@fda.hhs.gov>
Subject: Gilead FDA material

Hi Steve,

Please see attached the interim analysis for 53 CU patients and the draft expanded access treatment protocol.

These materials were sent to your team in preparation for a 9am call tomorrow morning between our teams to discuss.

Due to the nature of the interim analysis, I believe it would be helpful to have a discussion with you and Dr. Birx tomorrow when possible in addition to the team discussion. Can you let me know if you agree, and if you support me sharing the interim analysis with Dr. Birx?

If possible, I would prefer that we speak prior to this data being shared beyond FDA and Dr. Birx.

Please let me have your thoughts. I look forward to seeking your advice on next steps.

Best,
Dan

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/23/2020 6:47:22 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: Gilead FDA material
Attachments: protocol GS-US-540-5821_Aproved.pdf; CU Update for FDA_final.pptx

Thoughts? Let me know when you're free for a call.

Thanks

S

From: Daniel O'Day <daniel.oday@gilead.com>
Date: March 22, 2020 at 10:39:25 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Gilead FDA material

Hi Steve,

Please see attached the interim analysis for 53 CU patients and the draft expanded access treatment protocol.

These materials were sent to your team in preparation for a 9am call tomorrow morning between our teams to discuss.

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Best,
Dan

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/27/2020 2:00:02 PM
To: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Joe Grogan [Joseph.J.Grogan@who.eop.gov]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
Subject: Fwd: Chinese convalescent plasma pre-print in BMJ
Attachments: The feasibility of convalescent plasma therapy in severe COVID19 patients --a pilot study.2020.03.16.20036145v1.full.pdf

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Date: March 26, 2020 at 4:37:31 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: Chinese convalescent plasma pre-print in BMJ

Dear Dr. Hahn,
Colin had asked if I could forward the BMJ preprint on convalescent plasma from the early Chinese experience – it is attached.
Please let us know if you have any questions or need anything else on this.
Thanks,
Julie

Julia C. Tierney, JD
Chief of Staff

Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
(301) 796-8602 (direct)
Julia.Tierney@fda.hhs.gov



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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/24/2020 5:23:15 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: FDA encourages use of experimental coronavirus treatment made from survivors' blood

This is really good work.

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Date: March 24, 2020 at 5:09:53 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: FDA encourages use of experimental coronavirus treatment made from survivors' blood

FDA encourages use of experimental coronavirus treatment made from survivors' blood

By Arthur Allen

03/24/2020 05:08 PM EDT

FDA today encouraged researchers to study the experimental treatment of desperately ill Covid-19 patients with convalescent serum, a 130-year-old therapy that medicine periodically retrieves from its black bag with mixed success during pandemics.

The agency also said it would approve emergency use of the treatment — plasma rich with coronavirus antibodies, taken from the blood of people who have recovered from the disease — on severely ill patients. FDA said it would require donors' blood be carefully screened to make sure there was no residual coronavirus or other contaminants.

Convalescent serum was used to treat a variety of infections from the 1890s until around World War II. The 1925 dogsled trek that brought diphtheria "antitoxin" to save children in Nome, Alaska, is memorialized in the Balto movies and the annual Iditarod dog race.

More recently, Chinese doctors gave convalescent plasma to 21 patients during the 2009 swine flu pandemic; a fifth died, compared to 55 percent in a control group. The serum had almost no impact in Guinea when used in a group of Ebola patients in 2014. Chinese doctors have also employed human serum against coronavirus in the current pandemic.

Antibody therapy is most effective when used to prevent disease rather than in treatment, according to an article published last week by experts Arturo Casadevall of Johns Hopkins University and Liise-anne Pirofski of the Albert Einstein College of Medicine, who are organizing a trial to test the serum.

In contrast to the FDA, which said it would only give permission for emergency use in the sickest patients, Casadevall and Pirofski write that the serum might be most appropriate to temporarily boost protection in infected health care workers who would otherwise need to go into quarantine.

FDA provided emergency numbers for doctors to reach officials at the agency who can approve use of the therapy at short notice in the most desperate cases.

To view online:

<https://subscriber.politicopro.com/health-care/whiteboard/2020/03/fda-encourages-use-of-experimental-coronavirus-treatment-made-from-survivors-blood-3978431>

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1000 Wilson Blvd.
Arlington, VA 22209
USA.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/30/2020 7:56:22 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Need the CTAP graphics for my call with Joe Grogan at 7:45
Attachments: CTAP_print_3.29.20.pdf

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: March 30, 2020 at 7:09:38 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Need the CTAP graphics for my call with Joe Grogan at 7:45

Apologies for the delay – here is the current draft. Please let us know if you have any comments or edits. (b) (5)

[REDACTED]

--

Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, March 30, 2020 7:05 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Need the CTAP graphics for my call with Joe Grogan at 7:45

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/27/2020 8:25:03 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Chinese convalescent plasma pre-print in BMJ
Attachments: The feasibility of convalescent plasma therapy in severe COVID19 patients --a pilot study.2020.03.16.20036145v1.full.pdf

These are interesting and promising early results.

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Date: March 26, 2020 at 4:37:31 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
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Julia C. Tierney, JD
Chief of Staff

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Julia.Tierney@fda.hhs.gov



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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/24/2020 5:03:19 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: FW: Gilead FDA material
Attachments: protocol GS-US-540-5821_Aproved.pdf; CU Update for FDA_final.pptx

From: Daniel O'Day <daniel.oday@gilead.com>
Date: March 23, 2020 at 3:48:06 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Subject: FW: Gilead FDA material

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The bigger issue is [REDACTED] (b) (4)

[REDACTED]

Best,
Dan

From: Daniel O'Day <daniel.oday@gilead.com>
Date: Sunday, March 22, 2020 at 10:37 PM
To: "sh1@fda.hhs.gov" <sh1@fda.hhs.gov>
Subject: Gilead FDA material

Hi Steve,

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These materials were sent to your team in preparation for a 9am call tomorrow morning between our teams to discuss.

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Best,
Dan

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/20/2020 3:09:33 PM
To: Debi Birx MD [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
Subject: Fwd: CDC Summary for Clinicians on COVID Potential Therapies
Attachments: image002.png; ATT00001.htm; 20200319 Information for Clinicians on COVID-19 Therapies revised_FDA.docx; ATT00002.htm

(b) (5)

Sent from my iPad

Begin forwarded message:

From: "Guram, Jeet" <Jeet.Guram@fda.hhs.gov>
Date: March 20, 2020 at 2:18:47 PM EDT
To: "Hahn, Stephen" <SH1@fda.hhs.gov>
Cc: "Shah, Anand" <Anand.Shah@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>
Subject: CDC Summary for Clinicians on COVID Potential Therapies

Dr. Hahn, please see attached CDC's document with one comment that FDA has. Just let me know if you have any questions.

--

Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/16/2020 2:26:00 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; kac@who.eop.gov
Subject: Fwd: Blood Donation
Attachments: AABB-COVID-19-Outbreak-Checklist.docx

Kellyanne and Deb,

Here is the information about blood donation [REDACTED]

(b) (5)

[REDACTED] Please let me know how we can help.

Steve

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 16, 2020 at 2:09:01 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Blood Donation

Sir – The blood centers have the attached extensive checklist, but the long and the short of it is the following:

- Blood centers either have or are working on developing appointment calendars for individuals to donate, so that people don't have to wait in long lines
- Blood centers screen donors before they enter the donor room to make sure that they are healthy
- Staff are skilled at dealing with infection control practices from prior experience and will be taking all appropriate precautions to facilitate donor safety.

Just let me know if you need anything else. Dr. Marks is happy to brief anyone on this as need.

Thanks,
KL

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/13/2020 1:18:47 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Debi Bix [Deborah.L.Bix@nsc.eop.gov]
Subject: Re: Swabs/ Viral Transport Media Tubes

Jeff
Thx. Copying Dr. Bix. There are additional questions.
Steve

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: March 13, 2020 at 12:38:13 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Swabs/ Viral Transport Media Tubes

New FAQ just posted on our website that should help relieve some of the strains on specimen collection swab/tube availability and more under consideration,

Q: I am having trouble obtaining viral transport media/ universal transport media (VTM/UTM) to collect and transport patient samples. Are there alternatives that I can use?

A: While VTM/UTM remains the preferred transport media, FDA believes that the following alternative transport media could be used to collect and transport patient samples for molecular RT-PCR SARS-CoV-2 assays in a manner that will stabilize the RNA without meaningful degradation:

- Liquid Amies-based transport media.
 - Supplies:
 - E-Swab by Copan (Catalogue # 481C and 482C) with regular or flex minitip applicator
 - Opti-Swab by Puritan (Catalogue # LA-117), swab included in kit (Catalog#3317-H).
 - Storage: Up to 72 hours at 4°C, or frozen for longer storage.

If the above are not available, FDA believes that the following could be used to collect and transport samples for molecular RT-PCR SARS-CoV-2 assays:

- Dry swab in saline
 - Supplies:
 - Puritan: 25-3317-H, 25-3316-U, 25-3316-H, 25-3317-U, 25-3318-U, 25-3318-H, 3316-U, 3317-U, 3318-U, 25-3319-H, 3316-H, 3318-H, 25-3320-U, 25-3320-U EMB 100MM, 25-3320-U EMB 80MM, 25-3320-H and 25-3320-H EMB 80MM
 - Copan: 501CS01, 503CS01, 516CS01, 518CS01 and 534CS01
 - Storage: Up to 72 hours at 4°C, or frozen for longer storage.

Please be aware that the CDC does **not** recommend use of calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing.

We are continuing to evaluate other options for specimen collection supplies, and we will update this list accordingly as this information becomes available.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/13/2020 1:15:19 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: VTM

New FAQ just posted on our website that should help relieve some of the strains on specimen collection swab/tube availability and more under consideration,

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- Dry swab in saline
 - Supplies:
 - Puritan: 25-3317-H, 25-3316-U, 25-3316-H, 25-3317-U, 25-3318-U, 25-3318-H, 3316-U, 3317-U, 3318-U, 25-3319-H, 3316-H, 3318-H, 25-3320-U, 25-3320-U EMB 100MM, 25-3320-U EMB 80MM, 25-3320-H and 25-3320-H EMB 80MM
 - Copan: 501CS01, 503CS01, 516CS01, 518CS01 and 534CS01
 - Storage: Up to 72 hours at 4°C, or frozen for longer storage.

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Sent: 4/14/2020 5:04:55 PM
To: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Joe Grogan [Joseph.J.Grogan@who.eop.gov]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Follow up - samples needed for test developers

Bob,
Great to see you today [REDACTED] (b) (5)
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
Thanks
Steve

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/14/2020 4:53:19 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Would this help our efforts?

Debi

(b) (5)

thanks
Steve

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/12/2020 11:22:33 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS- (b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
Subject: Fwd: Retail Infographic - Best Practices for Retail During the COVID-19 Pandemic
Attachments: Best Practices_Retail_COVID.pdf

For your information. We created this for our regulated food industry.
Steve

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Date: April 11, 2020 at 11:19:56 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Retail Infographic - Best Practices for Retail During the COVID-19 Pandemic

Commissioner Hahn:

Yesterday, you asked that I share a copy of the retail infographic we created. (b) (5)

[REDACTED] As I think you know, in retail food settings, a significant percentage of front-line staff may not speak English as their primary language.

Therefore, for our retail guidance, we wanted to communicate in a way that relied less on words to enhance the communication and understanding process.

Attached a copy of the infographic, and below is a link to where it resides on our website.

<https://www.fda.gov/food/food-safety-during-emergencies/best-practices-retail-food-stores-restaurants-and-food-pick-updelivery-services-during-covid-19>

We've been told by one fast food chain, Chipotle, that they are giving a color copy to each employee and others have also said they've shared with all stores nationwide. We've also received requests for translation into other languages.

Small thing, but sometimes it's the little things that make a difference. And we know that with this virus, education to influence behavior change is critical to prevent transmission and strengthen prevention.

Frank Yiannas

Deputy Commissioner, Food Policy & Response

U.S. Food and Drug Administration

10903 New Hampshire Ave.

Silver Spring, Maryland 20993

Tel: 301-796-4665

frank.yiannas@fda.hhs.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/8/2020 9:50:51 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: Serology testing -CONFIDENTIAL AND PREDECISIONAL

FYI

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: April 8, 2020 at 9:49:31 AM EDT
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Serology testing -CONFIDENTIAL AND PREDECISIONAL

Jeff and Anand,

I wanted to give you feedback from yesterday's TF meeting (b) (5)

[REDACTED]

(b) (5)

(b) (5)

I am sorry for the long email. I'm happy for us to have a quick call to review and/or you can respond via email. Thanks for your hard work on this.
Steve

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/8/2020 9:15:07 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Serology Question Follow Up - BD

For the top of your inbox.
This request for help with respect to challenges faced in China.
Thanks, Joe

From: Dave Hickey <Dave_Hickey@bd.com>
Date: April 6, 2020 at 9:31:04 PM EDT
To: Whitaker, Scott <SWhitaker@AdvaMed.org>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Serology Question Follow Up - BD

Scott,

Thanks for forwarding

Dr Hahn – thank you again for taking time on the call today and for listening to our questions / asks and for the guidance from you and your team. Very much appreciated.

Dave.



Dave Hickey
President, Integrated Diagnostic Solutions

Dave.Hickey@bd.com

7 Loveton Circle,
Sparks, Maryland 21152
US
t: 4103164121
c: [REDACTED] (b) (6)

bd.com

From: Whitaker, Scott <SWhitaker@AdvaMed.org>
Sent: Monday, April 6, 2020 9:26 PM
To: Stephen Hahn <SH1@fda.hhs.gov>
Cc: Dave Hickey <Dave_Hickey@bd.com>
Subject: Fwd: Serology Question Follow Up - BD

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Dr. Hahn,

Per our earlier discussion, see below an email from Dave Hickey, President BD Integrated Diagnostic Solutions, outlining the challenges we are facing in China as well as a recommendation on CLIA. Thanks for your consideration.

Scott

Sent from my iPad

Scott, please find below an email to Commissioner Hahn to follow-up on the issue that I raised during today's AdvaMedDx Board discussion. As he requested, if you could feed this into him it would be really appreciated.

Commissioner Hahn,

Last week, we announced a partnership with BioMedomics and Henry Schein to bring a high quality serology test to the U.S. market (see release below). This will meet a critical need for new point-of-care test that can detect antibodies in blood to confirm current or past exposure to COVID-19 in as little as 15 minutes. At this point, we are facing two barriers to bringing this tests to patients.

The first is a new requirement that the Chinese government has put in place to limit low quality exports based on criticism China has received abroad. However, this is an instance of a high quality test that has been clinically validated at several hospitals and clinical laboratories in both the U.S. and China, and BioMedomics published clinical data in the Journal of Medical Virology was one of the world's first for a COVID-19 serology test (b) (4)

NMPA registration process for a product like this could take 2-3 years. We understand that a meeting was planned with USTR today to discuss this new requirement, and we hope that some type of waiver can be granted in this instance.

The second barrier is the EUA/CLIA waiver issue that we discussed during the call. It is encouraging that FDA will prioritize review of EUAs for these tests, and it is also critical that they are deemed CLIA-waived while an EUA is pending.

We look forward to working with you to ensure appropriate access to these critical tests.

Dave

BD, BioMedomics Announce Launch of Rapid Serology Test to Detect Exposure to COVID-19

Point-of-care blood test detects evidence of present or past exposure in 15 minutes

FRANKLIN LAKES, N.J. and MORRISVILLE, N.C., March 31, 2020 /PRNewswire [prnewswire.com]/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, and BioMedomics, a privately held, North Carolina-based clinical diagnostics company, today announced the release of a new point-of-care test that can detect antibodies in blood to confirm current or past exposure to COVID-19 in as little as 15 minutes.

The new test, developed and manufactured by BioMedomics, will be available through BD and distributed exclusively by Henry Schein, Inc. to health care providers throughout the United States.

The test does not require special equipment and may be used in a laboratory or at the point of care. The test detects antibodies in the blood that are produced by the body in response to coronavirus infection. These antibodies are

typically present in the middle to later stages of COVID-19 infection, but may remain present after exposure, which helps clinicians determine who has been exposed to the coronavirus, even if a person didn't exhibit any symptoms of the COVID-19 disease. Data on past exposure is important for researchers to more accurately understand the likely true occurrence of SARS-CoV-2 infection across a population. This information will be helpful in informing future strategies for combatting COVID-19.

"Serology tests are important because they provide an additional piece of information to aid in characterizing possible prior exposure to SARS-CoV-2, especially since many infections are mild or asymptomatic in severity," said Dave Hickey, president of Integrated Diagnostic Solutions for BD. "Initial evidence suggests that nearly all patients infected with SARS-CoV-2 will have developed a detectable antibody response within days of symptom onset, at which time a negative serologic test, along with molecular diagnostics, could be helpful in ruling out COVID-19. Our agreement with BioMedomics adds a rapid serology test that can augment current tests already on the market, and we are pleased to collaborate in this effort with Henry Schein, which has extensive knowledge of the point-of-care test field."

The test is completed in four, simple steps. First, blood is collected through normal blood collection devices such as the BD Microtainer® Contact-Activated Lancet. A few drops of blood are then transferred to the test cartridge, followed by two to three drops of a buffer. The results can be read in 15 minutes, similar to how over-the-counter pregnancy tests show multiple lines for positive results and a single line for negative results.

"BioMedomics designed the test to be easy to use and provide results in minutes, with no special equipment necessary or the need to transport the sample to a laboratory for analysis," said Frank Wang, CEO of BioMedomics. "Our test has been clinically validated at several hospitals and clinical laboratories in both the U.S. and China, and our published clinical data in the *Journal of Medical Virology* was one of the world's first for a COVID-19 serology test. It has been used widely in China during the COVID-19 outbreak and is now ready to help combat coronavirus in the U.S. through our collaboration with BD. We are committed to doing our part to battle this disease and are excited to have BD as a partner to help deliver our high-quality rapid test to those who need it most."

The test analyzes blood, serum or plasma samples for the presence of immunoglobulin M (IgM) and Immunoglobulin G (IgG) antibodies associated with the coronavirus (SARS-CoV-2). IgM provides the first line of defense during viral infections, followed by the generation of adaptive, high-affinity IgG responses for long-term immunity and immunological memory. The detection of COVID-19 IgM antibodies tends to indicate a recent exposure to COVID-19, and detection of COVID-19 IgG antibodies indicates a later stage of infection, so this combined antibody test could also provide information on the stage of the disease in patients. Current guidance from the U.S. Food and Drug Administration (FDA) recommends that results from antibody testing should not be used as the sole basis to diagnose or exclude coronavirus infection. Depending on the clinical scenario, additional testing, such as those used on the BD MAX™ System may be considered to further evaluate the possibility of SARS-CoV-2 infection.

"We look forward to working with such an outstanding company as BD to help make the antibody test part of the standard of care," said Stanley M. Bergman, Henry Schein's chairman of the board and chief executive officer. "The test will help to identify people who have developed antibodies to the virus, which may inform future strategies regarding COVID-19."

The test has not been reviewed by the FDA but is permitted for distribution and use under the public health emergency guidance issued by FDA on March 16, 2020, and BD expects to begin shipping tests in April. BD will have capacity to supply more than one million tests over the coming months, with the ability to scale up based on market demand and is working with medical products distribution company Henry Schein to make these tests available to medical care facilities throughout the United States. Health care providers can order the test and all collection devices needed to perform the test by contacting their BD or Henry Schein representatives.

About BD

BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 65,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit [bd.com \[c212.net\]](https://bd.com/c212.net).

About BioMedomics

BioMedomics is a point-of-care diagnostics company that aims to provide novel, rapid point-of-care tests to aid in the diagnosis of critical diseases. The company uses cutting-edge technology to create life-saving diagnostic solutions and address global health care needs. Its diagnostic tests produce rapid and accurate clinical results at the point-of-care without requiring complex and expensive lab equipment — placing immediate health care knowledge in the hands of providers. With that knowledge comes the power to make treatment decisions and save lives. Please visit biomedomics.com [c212.net] for more information.



Dave Hickey

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Corporate Headquarters Mailing Address: BD (Becton, Dickinson and Company) 1 Becton Drive Franklin Lakes, NJ 07417 U.S.A.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/9/2020 8:16:11 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Senate calls today

Debi,

Below are some questions that have been passed along to us from Senate Republicans. Could you chat before the call?

Thanks

Steve

This is about testing. Americans may not be willing to go back to work or back to 6000 colleges and 100,000 schools unless they know that they and many of their classmates or fellow workers don't have the virus.

So, One, do you agree that the goal should be to flood the country with free tests with quick results so you can know whether you HAVE the virus and whether you HAVE HAD the virus and are now likely immune, at least for the short-term?

Two, how many Americans will be tested, and receive results, on diagnostic and immunity tests in order to reach this goal by the end of June? July? And August?

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/7/2020 6:57:13 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Request

Joe,

(b) (5)

We will coordinate with HHS to identify the best POC going forward. Additional tactical details can be sorted out at that point.

Thanks
Steve

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/2/2020 4:40:30 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: First coronavirus blood test gets FDA emergency authorization

From: POLITICO Pro <politicoemail@politicopro.com>
Date: April 2, 2020 at 1:23:31 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: First coronavirus blood test gets FDA emergency authorization

First coronavirus blood test gets FDA emergency authorization

By David Lim

04/02/2020 01:20 PM EDT

The FDA has granted its first emergency use authorization for a coronavirus test that analyzes antibodies in a person's blood to determine if they have been exposed to the virus.

Antibody tests, also known as serology tests, are powerful weapons to curb outbreaks because they can detect people who have recovered from infection, not just those who are currently ill.

The serology test that received FDA authorization Wednesday is manufactured by Cellex. The agency says that "it is reasonable to believe" that Cellex's antibody test "may be effective in diagnosing" the virus and that there is no "adequate, approved, and available alternative." By contrast, devices seeking approval under a premarket approval application must show evidence that "provides reasonable assurance" they are "safe and effective."

Under guidance updated in March, FDA is allowing firms that validate coronavirus serological tests to use them in certain circumstances before being reviewed by the agency. More than 50 serological tests are being offered under that policy, according to an FDA document. Such tests must disclose they have not been reviewed by the agency, cannot be used for home testing and results from them "should not be used as the sole basis to diagnose or exclude" coronavirus exposure.

Earlier this week, the California company Bodysphere falsely claimed in a press release that it already received authorization for a coronavirus antibody test. An agency spokesperson told POLITICO today that the Cellex test is the only one to receive such authorization from FDA to date.

To view online:

<https://subscriber.politicopro.com/health-care/whiteboard/2020/04/first-coronavirus-blood-test-gets-fda-emergency-authorization-3978844>

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Sent: 4/7/2020 8:24:49 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Serology Question Follow Up - BD

As per our discussion, [REDACTED] (b) (5)

[REDACTED]
[REDACTED]
Thanks
Steve

From: Whitaker, Scott <SWhitaker@AdvaMed.org>
Date: April 6, 2020 at 9:25:55 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Hickey, David <Dave.Hickey@bd.com>
Subject: Fwd: Serology Question Follow Up - BD

Dr. Hahn,

Per our earlier discussion, see below an email from Dave Hickey, President BD Integrated Diagnostic Solutions, outlining the challenges we are facing in China as well as a recommendation on CLIA. Thanks for your consideration.

Scott

Sent from my iPad

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The first is a new requirement that the Chinese government has put in place to limit low quality exports based on criticism China has received abroad. However, this is an instance of a high quality test that has been clinically validated at several hospitals and clinical laboratories in both the U.S. and China, and BioMedomics published clinical data in the Journal of Medical Virology was one of the world's first for a COVID-19 serology test. Our original plan was to have 100,000 of these tests available this week (450,000 tests in following weeks), but we had to cancel our shipment on Friday. The NMPA registration process for a product like this could take 2-3 years. We understand that a meeting was

planned with USTR today to discuss this new requirement, and we hope that some type of waiver can be granted in this instance.

The second barrier is the EUA/CLIA waiver issue that we discussed during the call. It is encouraging that FDA will prioritize review of EUAs for these tests, and it is also critical that they are deemed CLIA-waived while an EUA is pending.

We look forward to working with you to ensure appropriate access to these critical tests.

Dave

BD, BioMedomics Announce Launch of Rapid Serology Test to Detect Exposure to COVID-19

Point-of-care blood test detects evidence of present or past exposure in 15 minutes

FRANKLIN LAKES, N.J. and MORRISVILLE, N.C., March 31, 2020 /PRNewswire [\[prnewswire.com\]](https://prnewswire.com/)/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, and BioMedomics, a privately held, North Carolina-based clinical diagnostics company, today announced the release of a new point-of-care test that can detect antibodies in blood to confirm current or past exposure to COVID-19 in as little as 15 minutes.

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"Serology tests are important because they provide an additional piece of information to aid in characterizing possible prior exposure to SARS-CoV-2, especially since many infections are mild or asymptomatic in severity," said Dave Hickey, president of Integrated Diagnostic Solutions for BD. "Initial evidence suggests that nearly all patients infected with SARS-CoV-2 will have developed a detectable antibody response within days of symptom onset, at which time a negative serologic test, along with molecular diagnostics, could be helpful in ruling out COVID-19. Our agreement with BioMedomics adds a rapid serology test that can augment current tests already on the market, and we are pleased to collaborate in this effort with Henry Schein, which has extensive knowledge of the point-of-care test field."

The test is completed in four, simple steps. First, blood is collected through normal blood collection devices such as the BD Microtainer® Contact-Activated Lancet. A few drops of blood are then transferred to the test cartridge, followed by two to three drops of a buffer. The results can be read in 15 minutes, similar to how over-the-counter pregnancy tests show multiple lines for positive results and a single line for negative results.

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"We look forward to working with such an outstanding company as BD to help make the antibody test part of the standard of care," said Stanley M. Bergman, Henry Schein's chairman of the board and chief executive officer. "The test will help to identify people who have developed antibodies to the virus, which may inform future strategies regarding COVID-19."

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Dave Hickey

President, Integrated Diagnostic Solutions

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Sent: 4/1/2020 6:37:51 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Subject: Accepted: Operational Check-in
Location: Roosevelt Room
Start: 4/3/2020 1:30:00 PM
End: 4/3/2020 2:00:00 PM
Recurrence: (none)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/1/2020 6:37:50 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Subject: Accepted: Operational Check-in
Location: WHSR Exec
Start: 4/2/2020 1:15:00 PM
End: 4/2/2020 2:00:00 PM
Recurrence: (none)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/3/2020 11:59:15 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: A victory! New sanitizer supplies coming nationwide. Thank you. Question on donation?

From: Hayden, Lou <lou.hayden@lowes.com>
Date: April 3, 2020 at 11:33:19 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: Russo, Joseph H. EOP/WHO <Joseph.H.Russo@who.eop.gov>, Tim Pataki <Timothy.A.Pataki@who.eop.gov>
Subject: A victory! New sanitizer supplies coming nationwide. Thank you. Question on donation?

Drs. Hahn, Shah, and Kadlec, and Joe and Tim –

Thank you for your attention to help prioritize the expedited and thorough review for FDA approval for new Moxie-brand hand sanitizer to serve our 18 million customers a week nationwide, including first responders nationwide.

By the time the product flows into our distribution / store network, it will be early May.

Question: Since the government may have ongoing demand for essential materials, could we make a direct donation of 10,000 of the first units of hand sanitizer when they arrive in early May?

(Lowe's has already made \$175 million in COVID-related contributions, including \$10 million in products to responders, \$ to the Red Cross, donating all N-95 masks, and direct cash bonuses to our working hourly employees.)

With warm regards,

Lou

Lou Hayden
Head of Washington, DC Office
Lowe's Companies
300 New Jersey Avenue NW, Ste. 900
Washington, DC 20001
202-464-2780

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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/2/2020 4:40:31 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
Subject: Fwd: First coronavirus blood test gets FDA emergency authorization

From: POLITICO Pro <politicoemail@politicopro.com>
Date: April 2, 2020 at 1:23:31 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: First coronavirus blood test gets FDA emergency authorization

First coronavirus blood test gets FDA emergency authorization

By David Lim

04/02/2020 01:20 PM EDT

The FDA has granted its first emergency use authorization for a coronavirus test that analyzes antibodies in a person's blood to determine if they have been exposed to the virus.

Antibody tests, also known as serology tests, are powerful weapons to curb outbreaks because they can detect people who have recovered from infection, not just those who are currently ill.

The serology test that received FDA authorization Wednesday is manufactured by Cellex. The agency says that "it is reasonable to believe" that Cellex's antibody test "may be effective in diagnosing" the virus and that there is no "adequate, approved, and available alternative." By contrast, devices seeking approval under a premarket approval application must show evidence that "provides reasonable assurance" they are "safe and effective."

Under guidance updated in March, FDA is allowing firms that validate coronavirus serological tests to use them in certain circumstances before being reviewed by the agency. More than 50 serological tests are being offered under that policy, according to an FDA document. Such tests must disclose they have not been reviewed by the agency, cannot be used for home testing and results from them "should not be used as the sole basis to diagnose or exclude" coronavirus exposure.

Earlier this week, the California company Bodysphere falsely claimed in a press release that it already received authorization for a coronavirus antibody test. An agency spokesperson told POLITICO today that the Cellex test is the only one to receive such authorization from FDA to date.

To view online:

<https://subscriber.politicopro.com/health-care/whiteboard/2020/04/first-coronavirus-blood-test-gets-fda-emergency-authorization-3978844>

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FDA-OC-2020-2523-000535

HHS-FDA-20-0498-D-000052

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1000 Wilson Blvd.

Arlington, VA 22209

USA .

From: Mail Delivery System [MAILER-DAEMON@fda-ifw-00.fda.gov]
Sent: 3/30/2020 7:28:52 AM
To: Joseph.J.Grogan@who.eop.gov
Subject: Undeliverable: Need the CTAP graphics for my call with Joe Grogan at 7:45
Attachments: Fwd: Need the CTAP graphics for my call with Joe Grogan at 7:45

Your message

To: Joe Grogan
Subject: Fwd: Need the CTAP graphics for my call with Joe Grogan at 7:45
Sent: 3/30/2020 7:27:46 AM

The following message to <Joseph.J.Grogan@who.eop.gov> was undeliverable.
The reason for the problem:
5.1.1.0 - Unknown address error 552-'size limit exceeded'

From: Mail Delivery System [MAILER-DAEMON@fda-ifw-00.fda.gov]
Sent: 3/31/2020 12:40:39 PM
To: Joseph.J.Grogan@who.eop.gov
Subject: Undeliverable: Please send to me
Attachments: Fwd: Please send to me

Your message

To: Joe Grogan
Subject: Fwd: Please send to me
Sent: 3/31/2020 12:35:17 PM

The following message to <Joseph.J.Grogan@who.eop.gov> was undeliverable.
The reason for the problem:
5.1.1.0 - Unknown address error 552-'size limit exceeded'

From: Mail Delivery System [MAILER-DAEMON@fda-ifw-00.fda.gov]
Sent: 3/30/2020 12:04:41 PM
To: Joseph.J.Grogan@who.eop.gov
Subject: Undeliverable: Updated CTAP Graphic
Attachments: Fwd: Updated CTAP Graphic

Your message

To: Joe Grogan
Subject: Fwd: Updated CTAP Graphic
Sent: 3/30/2020 12:01:51 PM

The following message to <Joseph.J.Grogan@who.eop.gov> was undeliverable.
The reason for the problem:
5.1.1.0 - Unknown address error 552-'size limit exceeded'

From: Mail Delivery System [MAILER-DAEMON@fda-ifw-00.fda.gov]
Sent: 3/30/2020 7:57:06 AM
To: Joseph.J.Grogan@who.eop.gov
Subject: Undeliverable: Need the CTAP graphics for my call with Joe Grogan at 7:45
Attachments: Fwd: Need the CTAP graphics for my call with Joe Grogan at 7:45

Your message

To: Joe Grogan
Subject: Fwd: Need the CTAP graphics for my call with Joe Grogan at 7:45
Sent: 3/30/2020 7:56:22 AM

The following message to <Joseph.J.Grogan@who.eop.gov> was undeliverable.
The reason for the problem:
5.1.1.0 - Unknown address error 552-'size limit exceeded'

From: Mail Delivery System [MAILER-DAEMON@fda-ifw-00.fda.gov]
Sent: 3/30/2020 7:55:16 AM
To: Joseph.J.Grogan@who.eop.gov
Subject: Undeliverable: Need the CTAP graphics for my call with Joe Grogan at 7:45
Attachments: Fwd: Need the CTAP graphics for my call with Joe Grogan at 7:45

Your message

To: Joe Grogan
Subject: Fwd: Need the CTAP graphics for my call with Joe Grogan at 7:45
Sent: 3/30/2020 7:54:20 AM

The following message to <Joseph.J.Grogan@who.eop.gov> was undeliverable.
The reason for the problem:
5.1.1.0 - Unknown address error 552-'size limit exceeded'

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/20/2020 3:08:19 PM
To: Debi Birx MD [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-H (b) (6)]
Subject: Fwd: CDC Summary for Clinicians on COVID Potential Therapies
Attachments: image002.png; ATT00001.htm; 20200319 Information for Clinicians on COVID-19 Therapies revised_FDA.docx; ATT00002.htm

(b) (6)

Sent from my iPad

Begin forwarded message:

From: "Guram, Jeet" <Jeet.Guram@fda.hhs.gov>
Date: March 20, 2020 at 2:18:47 PM EDT
To: "Hahn, Stephen" <SH1@fda.hhs.gov>
Cc: "Shah, Anand" <Anand.Shah@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>
Subject: CDC Summary for Clinicians on COVID Potential Therapies

Dr. Hahn, please see attached CDC's document with one comment that FDA has. Just let me know if you have any questions.

--

Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Mail Delivery System [MAILER-DAEMON@smtp6.fda.gov]
Sent: 4/22/2020 3:08:00 PM
To: (b) (6)@cea.eop.gov
Subject: Undeliverable: TO BE RESCHEDULED: Telecon: CEA/FDA Discussion
Attachments: TO BE RESCHEDULED: Telecon: CEA/FDA Discussion

Your message

To: (b) (6)@cea.eop.gov; Williams, James H. EOP/WHO (b) (6)@cea.eop.gov; Grogan, David N. EOP/CEA; Shah, Anand; Lenihan, Keagan; Rom, Colin; Schiller, Lowell
Subject: TO BE RESCHEDULED: Telecon: CEA/FDA Discussion
Sent: 4/22/2020 3:07:15 PM

The following message to (b) (6)@cea.eop.gov was undeliverable.
The reason for the problem:
5.1.0 - Unknown address error 550-'#5.1.0 Address rejected.'

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/28/2020 7:52:51 AM
To: Watts, Mary Lee [mwatts@asmusa.org]; 'Birx, Deborah L. EOP/NSC' [Deborah.L.Birx@nsc.eop.gov]
CC: Segal, Allen [asegal@asmusa.org]; Bertuzzi, Stefano [sbertuzzi@asmusa.org]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Subject: RE: Thank you

I'd be very happy to meet with Dr. Patel while we are at Mayo, schedule permitting. Do you have contact information? I really appreciate your reaching out. I'm copying Janice.
Steve

From: Watts, Mary Lee <mwatts@asmusa.org>
Date: April 27, 2020 at 5:06:27 PM EDT
To: 'Birx, Deborah L. EOP/NSC' <Deborah.L.Birx@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Segal, Allen <asegal@asmusa.org>, Bertuzzi, Stefano <sbertuzzi@asmusa.org>
Subject: RE: Thank you

Dear Dr. Birx,

Thank you so much for your reply. I hope that at some point you will have the opportunity to meet Dr. Patel. We appreciate everything that you and your team, including Nelson Michael, are doing to assist our clinical laboratory members.

Dear Dr. Hahn,

If your schedule on Wednesday permits, we would be glad to work with you and your staff to arrange for you to meet Dr. Patel while at Mayo. We have had a ongoing, productive dialogue with Jeff Shuren and his team since late February about COVID-19 testing concerns. Dr. Patel has been a part of those discussions and we'd welcome the chance for her to connect with you on this.

I look forward to hearing from you both about how you would like to proceed. I have copied ASM's CEO, Dr. Stefano Bertuzzi and ASM's Director of Policy and Advocacy Allen Segal here as well.

Best,
Mary Lee

Mary Lee Watts, MPH, RD
Director, Federal Affairs
Public Policy and Advocacy
American Society for Microbiology
1752 N St., NW
Washington, DC 20036
Cell: 571-228-8345
mwatts@asmusa.org

From: Birx, Deborah L. EOP/NSC [mailto:Deborah.L.Birx@nsc.eop.gov]

Sent: Monday, April 27, 2020 4:20 PM

To: Watts, Mary Lee <mwatts@asmusa.org>

Cc: Stephen Hahn <sh1@fda.hhs.gov>

Subject: Thank you

I would love to see the ASM president. I am so grateful for all the work you have done. Dr Hahn will be there and please have them meet.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/2/2020 6:57:49 PM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: Fwd: New Understanding of Covid Infection
Attachments: Oak Ridge Nasal to GI spread 2020.pdf

Interesting, particularly the fecal-oral issues.
Steve

From: John Kennedy <john@johnkennedy.com>
Date: May 2, 2020 at 1:12:20 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: New Understanding of Covid Infection

Stephen, John Kennedy from the Senate here. Thank you for our conference call. Very helpful. Please see below from Dr. Tom Kennedy, a pulmonologist and research scientist, about how the virus spreads. Could it be that adding and closing lids on toilets (especially in public restrooms) before flushing might impede transmission? Please share with your colleagues on the Pence Task Force as you see fit. Thanks, Mr. Commissioner. You have been a rock star through all this. Best, John

Sent from my iPad

Begin forwarded message:

From: "Kennedy, Thomas P" <tkenned7@tulane.edu>
Date: May 1, 2020 at 10:38:05 PM CDT
To: John Kennedy <john@johnkennedy.com>
Subject: New Understanding of Covid Infection

John,

I spent the afternoon at an NIH seminar on glycobiology (sugars) and Covid infection. There was a fascinating talk from Oak Ridge National Laboratory, attached.

They believe that infection starts in cells in the nose and tongue, which have the ACE2 receptor. There virus begins to replicate, and patients are infectious but not symptomatic. Instead of going to the lung, the virus is swallowed and infects the cells of the small and large intestine, which express high levels of the ACE2 receptor. The lung does not. In the gut, the virus really gets going and producing more particles, shed in the stool. This is the time one first has an immune response and has a fever. From the intestine, the virus spreads through the lymphatics up through the central lymphatic drainage channel to the chest, where it empties into the venous circulation. Then it gets access to the lung as blood is pumped from the right heart. The lung infection does not occur down the airway but from the blood stream. This fits with the types of pneumonia one sees, consisting of pneumonia at the bottoms of the lung, where blood flow is greatest.

This sequence fits best with the long time of shedding before symptoms of cough and shortness of breath. This has big implications about where the risk is in reopening. They pointed out that commercial toilets have a very powerful

aerosol generating plume that goes up about 3 feet from the water surface in the bowl. That could contain a lot of virus. In home bathrooms, one can stop this plume by closing the lid before flushing. Commercial toilets have no lid. Therefore they believe that public bathrooms will be big potential sources of spread from viral shedding in the stool.

This idea fits with a headline from the Post today, discussing that one can track levels of infection in a community by sampling levels of viral RNA in sewerage at treatment plants: <https://www.washingtonpost.com/climate-environment/2020/05/01/coronavirus-sewage-wastewater/>

I suppose the CDC gets this but I wonder if they may wish to address the issue of potential spread in communal toilets and the risk that they could provide, if this scenario is correct. Hard to think about putting lids on commercial toilets, but it would not be an impossible task.

Tom

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/1/2020 8:47:11 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Testing Centers
Attachments: POCT COVID Testing_4.24.pptx

Thought this might be of interest to you. Anand Shah from my office is following up with Dr. Brennan. Steve

From: Merlo, Larry J. <Larry.Merlo@CVSHealth.com>
Date: April 30, 2020 at 9:53:26 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Brennan, Troyen A. <Troyen.Brennan@CVSHealth.com>
Subject: Testing Centers

Dr. Hahn,

It was great spending a few minutes with you on Monday.

Attached is a summary of our Point of Care Testing at our large-scale sites. This data is approximately one week old, and we would now be at approximately 70k individuals tested.

I am copying Dr. Troyen (Troy) Brennan, our Chief Medical Officer, to connect the two of you for additional discussion.

Best regards,

Larry Merlo | President & CEO, CVS Health
p 401-770-2340
1 CVS Drive, Mail Code 1000, Woonsocket, RI 02895



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Sent: 4/21/2020 8:52:03 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (5) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: Fwd: Nation COVID-19 Diagnostic Testing Strategy Needed to Expand Laboratory Test Capacity

Colleagues,

See below. I am also receiving a lot of questions about strategy for diagnostics and serology moving forward. Some of our FDA-regulated industries (food processing, in particular) are asking about the use of our authorized diagnostic tests to screen asymptomatic workers. (b) (5)

[REDACTED]

[REDACTED]

From: Shelia Metcalf <smetcalf@madisoncountync.gov>
Date: April 21, 2020 at 12:59:32 PM EDT
To: FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
Subject: Nation COVID-19 Diagnostic Testing Strategy Needed to Expand Laboratory Test Capacity

Shelia Metcalf
493 Medical Park Drive
Marshall, NC 28753

April 21, 2020

Dear Stephen M. Hahn,

Dear Mr. President:

I am writing to urge you to develop a national COVID-19 diagnostic testing strategy. Experts believe that we can't effectively fight the COVID-19 pandemic without significantly enhancing our nation's COVID-19 laboratory testing capacity.

Since the federal government permitted commercial clinical laboratories, such as hospitals, academic medical centers, and reference laboratories, to develop their own laboratory tests to diagnose COVID-19, laboratories across the United States have performed 2 million tests for the virus. And, yet it's nowhere near enough. Unfortunately, many laboratories are suffering from a severe shortage of supplies necessary to increase test capacity for the virus causing COVID-19. Supplies, such as reagents, swabs, viral transport media, and personnel protective equipment, are in short supply. Often, the supplies that are available are more expensive than usual, adding to the already significant financial challenges America's diagnostic laboratories are facing.

To get America's testing capacity to where it needs to be, our clinical laboratories need help from the federal government. We need a national strategy to comprehensively identify and tackle the issues adversely affecting the ability of the nation's anatomic pathology and clinical laboratories to increase COVID-19 test capacity.

Key elements of a national strategy should include the following: improved coordination between federal and state governments, clinical laboratories and local Health Departments to increase test capacity and ensure the timely provision of personal protective equipment; support for our nation's laboratories needs to include a supply chain distribution model that will ensure that laboratory testing supply shortages (e.g., swabs, viral transport media, etc.) are addressed immediately; the integration of accurate and reliable laboratory tests needs to be coordinated with the appropriate experts; financial support for key healthcare professionals, such as pathologists, residents, laboratory professionals and the Local Health Departments that are on the front line doing the testing: in the form of hazard pay, loan forgiveness, etc.; and financial support for anatomic and clinical laboratories struggling with lost revenues and higher costs for needed testing supplies, like testing equipment, reagents, RNA extraction kits, and personal protective equipment.

Ensure small rural counties have the same opportunities as the bigger richer counties; we matter too. Give us the same advantages as the counties with money have (such as rapid tests, personal protective equipment, and supplies).

Hundreds of thousands of American lives are at risk. Developing a national testing diagnostic and screening tests is imperative to ending the pandemic, and reopening the American economy and getting Americans back to work.

Thank you.

Sincerely,
Shelia Metcalf

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/21/2020 3:27:39 PM
To: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9d983419fcd-HHS-olx1-cd]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Serology testing in Germany

FYI -- Our FDA Europe Office is still working on trying to obtain the information on serology testing in Germany from BfArM and others. No reply from BfArM yet. They did come across the following, translated from an article in German, that may be of interest:

The RKI [Robert Koch Institute] will soon start investigations on blood donors and humans in some COVID-19 outbreak areas. In the longer term, a nationwide representative study is planned. For laboratory analysis, the RKI works closely with the Institute for Virology at Charité - Universitätsmedizin Berlin, headed by Prof. Christian Drosten. The studies at a glance: Serological testing on blood donors in Germany: In cooperation with the blood donation services, blood samples from adults from all over Germany are regularly tested for antibodies. This allows conclusions to be drawn about the spread of SARS-CoV-2 in the population. Starting next week, approximately 5,000 blood samples will be tested every 14 days. First results are expected in early May 2020. Seroepidemiological studies at several particularly affected locations ("hotspots") in Germany: The aim of the localized studies is to estimate the immunity in the local population by determining antibodies against SARS-CoV-2 in representative samples of the inhabitants. The aim is also to better estimate the proportion of asymptomatic infections and risk factors for a severe course in the population. In each location, about 2,000 test persons aged 18 years and older will be examined several times. In addition, the test persons will be questioned about clinical symptoms, previous illnesses, health behaviour, living conditions and mental health. The study is scheduled to start in mid-April 2020, with initial results expected in May 2020. In planning and conducting these so-called "hotspot" studies, the RKI is cooperating with researchers around Prof. Gérard Krause from the Helmholtz Centre for Infection Research in Braunschweig. Nationwide population-representative seroepidemiological study: By determining antibodies against SARS-CoV-2 in a nationwide representative sample, the actual spread, immunity, the proportion of asymptomatic infections, the actual mortality rate and risk factors for a severe course in the German population will be better estimated. The study will involve 15,000 people aged 18 years and older at 150 study sites. The subjects will also be asked about clinical symptoms, previous illnesses, health behaviour, living conditions and mental health. The study is expected to start in mid-May 2020, and the first results are expected in June 2020.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/23/2020 9:34:42 AM
To: Sheila Peel [speel@hivresearch.org]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: Re: [EXTERNAL] RUO and EUA

Copying Jeff Shuren the Director of CDRH

From: Sheila Peel <speel@hivresearch.org>
Date: April 22, 2020 at 10:48:22 AM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: [EXTERNAL] RUO and EUA

Ma'am, Sir,

Thank you.

V/r
Sheila

Sheila A Peel, MSPH, PhD, DAC
Director, Diagnostics and Countermeasures Branch
Laboratory Director, HDRL, LDL
Center Infectious Disease Research
Walter Reed Institute of Research
503 Robert Grant Ave; Rm 1A32
Silver Spring, MD 30910
Office: 301-319-2297
iphone: (b) (6)
speel@hivresearch.org
Sheila.a.peel2.civ@mail.mil

From: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>
Date: Tuesday, April 21, 2020 at 4:59 PM
To: Sheila Peel <speel@hivresearch.org>
Cc: "Hahn, Stephen" <SH1@fda.hhs.gov>
Subject: [EXTERNAL] RUO and EUA

ATTENTION: This email originated from outside of the organization.
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Dr Hahn said they can be one thing. Deb

This message contains information that may be confidential, privileged, proprietary, or otherwise protected. If you are not the intended recipient, notify the sender immediately and delete/destroy all copies of this message

and any attachments. This message is not intended to constitute or include either an electronic record or an electronic signature unless otherwise specifically indicated.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/21/2020 3:25:03 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Follow up

Debi,

This is from the Illumina platform as per your request. We have their permission to release this information to you.

thanks and let me know if you need anything else.

Steve

Thank you for reaching out. There are currently (b) (4) Active NovaSeqs installed in the United States. Of those, we believe (b) (4) are in CLIA facilities and therefore assumed to be able to report patient results. (b) (4)

(b) (4). As you are likely aware, some of the testing constraints will be driven by the ability of labs to accession and process the samples for sequencing.

Some considerations in determining testing capacity include:

1. Given sample inflow volume (which will vary by day by site) and the need for fast turnaround time of results, labs may have some level of inefficiency and may have to conduct NovaSeq runs with fewer than 3,072 samples per run
2. There are likely a subset of customers who don't have adequate infrastructure for automation or upfront sample processing. We are actively assessing the sample accessioning and automation capabilities by site to determine the number of active NovaSeqs we expect to be running COVID testing.
3. Some NovaSeqs may be running other critical testing, such as cancer testing, and cannot be diverted to COVID.

(b) (4)



From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/17/2020 1:01:00 PM
To: Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: v6 Testing Strategy_FDA options for supplies.pptx
Attachments: v6 Testing Strategy_FDA options for supplies.pptx

Please let me know if you need anything more.

Thanks

Steve

From: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Sent: 5/27/2020 8:25:52 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Not ready for primetime but want your thoughts

Our team created this cartoon.
Thoughts?
Steve

(b) (5)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/14/2020 12:22:39 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Fwd: COVID diagnostics

Background for our call.
Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: May 14, 2020 at 9:49:10 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COVID diagnostics

Dear Steve,

Yes, fine to share email. The attachment was more related to (b) (4).

For clarity here are the 5 items I regard as follow up.

1. As states prepare scaling their COVID testing plan, they want HHS advice on what is FDA approved, what is supply capacity etc who are contacts etc. Our team had a separate request from the White House around providing technical assistance prior to a webinar for states that Dr. Birx wanted to host, but my understand is at this point, the webinar is not set up.
2. We had discussed the concept of FDA support in innovation, together with NIH Francis Collins and Bruce Tromberg at NIBIB in areas like automation, sample pooling, direct qPCR, as the FDA does in other areas of regulatory innovation (eg Precision medicine gene therapy)
3. Serology pre submission from our WuXi/Mayo collaboration (<https://thermofisher.mediaroom.com/2020-05-13-Thermo-Fisher-Scientific-Response-to-COVID-19-Expands-to-Include-New-Serology-Test>)
4. After action report (when quieter)
5. Vaccine capacity for surge: I learnt our team had a call with Peter Marks and his team Monday afternoon along with our quality leaders to discuss (b) (4). Follow up meetings are planned.

Regards

Mark

From: Steve Hahn <SH1@fda.hhs.gov>
Date: Thursday, May 14, 2020 at 8:31 AM
To: Mark Stevenson <mark.stevenson@thermofisher.com>
Cc: "Sheehy, Janice" <Janice.Sheehy@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Subject: Re: COVID diagnostics

CAUTION: This email originated from outside of Thermo Fisher Scientific. If you believe it to be suspicious, report using the Report Phish button in Outlook or send to SOC@thermofisher.com.

Mark,

We are setting up a call with Dr. Birx and Jeff Shuren. Is it ok if I share this email and the attachments with Dr. Birx prior to the call?

Thanks

Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>

Date: May 10, 2020 at 8:17:11 AM EDT

To: Hahn, Stephen <SH1@fda.hhs.gov>

Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

Steve

Janice and my assistant are connected and to arrange a call. Plenty of topics to cover around public health.

Our submissions to amendment to our FDA EUA to expand our qPCR platforms and protocols was approved which will greatly expand platforms already installed able to run the COVID19 assay, including in a 384 well throughput. We have also been discussing with Francis Collins at NIH expanding further throughput to a 10k/24hr period on NIH campus and other innovations eg thinking about group testing for sentinel surveillance following a Robert Dorfman method, all of which will require a continued partnership with FDA and CDC.

(b) (4)

answer any questions you may have, and continue our discussions as soon practicable, as we prepare to be ready to act upon these proposals in short order.

Best Mark

From: Steve Hahn <SH1@fda.hhs.gov>

Date: Saturday, May 9, 2020 at 10:14 AM

To: Mark Stevenson <mark.stevenson@thermofisher.com>

Cc: "Sheehy, Janice" <Janice.Sheehy@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>

Subject: Re: COVID diagnostics

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thank you very much for your message. Great work on all counts. We very much appreciate the work with Thermo Fisher. It would be great to arrange a call in the upcoming week. I'll ask Janice to arrange.

I am in self-quarantine but doing well.

Best
Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>

Date: May 9, 2020 at 9:53:38 AM EDT

To: Hahn, Stephen <SH1@fda.hhs.gov>

Subject: COVID diagnostics

Dear Steve,

I had read you will self-quarantine for 14 days after exposure to White House spokesperson Katie Miller, who tested positive for Covid-19 on Friday, so it prompted me to send a note. I hope you remain negative but I know you will have plenty of access to FDA EUA tests!

Quick update from Thermo Fisher. Your team has continued to be incredibly responsive providing feedback as we continue to expand use of our qPCR based testing to increase the platforms and workflows available for us which will expand testing capacity to reopen the economy. (b) (4)

We have also followed up on the work done with Mayo Clinic on ELISA lab based serology testing and signed an agreement with (b) (4) for that test for total antibodies (IgM/IgG). We will make a submission for that serology test will be coming to the FDA in the next few weeks.

We have also engaged with the NIH on their RADx to continue to innovate around diagnostic testing for COVID.

Let me know if we can be helpful during this unprecedented times. I'm sure at some point we can also spend time to share observations and lessons learnt in a post COVID world for how industry and FDA work together.

Best Mark

Mark Stevenson
Executive Vice President and
Chief Operating Officer

Thermo Fisher Scientific
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From: Mail Delivery System [MAILER-DAEMON@smtp7.fda.gov]
Sent: 4/20/2020 12:37:34 PM
To: (b) (6)@cea.eop.gov
Subject: Undeliverable: Telecon: CEA/FDA Discussion
Attachments: Telecon: CEA/FDA Discussion

Your message

To: (b) (6)@cea.eop.gov; Williams, James H. EOP/WHO; (b) (6)@cea.eop.gov; Grogan, David N. EOP/CEA; Shah, Anand; Lenihan, Keagan; Rom, Colin
Subject: Telecon: CEA/FDA Discussion
Sent: 4/20/2020 12:37:20 PM

The following message to (b) (6)g@cea.eop.gov> was undeliverable.
The reason for the problem:
5.1.1.0 - Unknown address error 550-'#5.1.0 Address rejected.'

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/31/2020 12:35:06 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Please send to me

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: March 31, 2020 at 12:06:13 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Please send to me

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/31/2020 7:47:07 AM
To: McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: potential call

(b) (5)

Do you have a POC and number?
Steve

From: McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Date: March 30, 2020 at 6:57:17 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: FW: potential call

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/31/2020 12:33:07 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Campana, Alexandra D. EOP/WHO (b) (6)@who.eop.gov
Subject: Re: Schedule of therapies coming on line

Pages 2 and 3 of the document I gave you yesterday.
S

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: March 31, 2020 at 11:25:28 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Campana, Alexandra D. EOP/WHO <Alexandra.D.Campana2@who.eop.gov>
Subject: Re: Schedule of therapies coming on line

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/31/2020 1:35:10 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: Confidential Draft Press Release

FYI

From: Daniel O'Day <daniel.oday@gilead.com>
Date: March 31, 2020 at 1:34:12 PM EDT
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Brett Pletcher <Brett.Pletcher@gilead.com>
Subject: Confidential Draft Press Release

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/30/2020 12:01:50 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Updated CTAP Graphic

We're putting it in landscape version but wanted you to see most recent version.
Steve

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: March 30, 2020 at 11:55:11 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: Updated CTAP Graphic

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/31/2020 11:04:03 AM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Campana, Alexandra D. EOP/WHO [Alexandra.D.Campana2@who.eop.gov]
Subject: Re: Schedule of therapies coming on line

Yes I handed it to you yesterday at the 2 pm meeting. I tried to email it multiple times yesterday (as I mentioned) but couldn't get through the WH gateway. I'm ready to present whenever you want me to do so

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: March 31, 2020 at 10:45:20 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Campana, Alexandra D. EOP/WHO <Alexandra.D.Campana2@who.eop.gov>
Subject: Schedule of therapies coming on line

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/31/2020 1:32:26 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: CORONAVIRUS FLAG: First cell treatment to fight coronavirus awaits FDA approval for clinical trial

Thx Joe

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: March 31, 2020 at 1:07:00 PM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: CORONAVIRUS FLAG: First cell treatment to fight coronavirus awaits FDA approval for clinical trial

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/1/2020 12:34:21 PM
To: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Joe Grogan (Joseph.J.Grogan@who.eop.gov) [Joseph.J.Grogan@who.eop.gov]
Subject: Re: Slides for noon teleconference

Thx

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Date: April 1, 2020 at 12:31:48 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Joe Grogan (Joseph.J.Grogan@who.eop.gov) <Joseph.J.Grogan@who.eop.gov>
Subject: FW: Slides for noon teleconference

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/1/2020 8:11:21 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Polowczyk, John P RADM USN JS J4 (USA) [john.p.polowczyk.mil@mail.mil]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
CC: Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]
Subject: Fwd: Ventilator Utilization Matrix for University of Washington Medical Center

Good morning,

I thought your teams would be interested from the front lines re: Utilization matrix for ventilators. This comes from the University of Washington. Dr. Josh Benditt went through this on Saturday's CMS doctors call. Not sure who would own this from a guidelines point of view but thought I would share.

Thanks

Steve

From: Czeka, Alina (CMS/CMMI) <Alina.Czeka@cms.hhs.gov>
Date: March 31, 2020 at 9:55:32 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: Ventilator Utilization Matrix for University of Washington Medical Center

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/15/2020 6:02:13 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
CC: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]
Subject: Re: Issue for VP TF

Thanks

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: April 15, 2020 at 6:01:04 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: Issue for VP TF

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/15/2020 5:14:27 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: FW: Devices received by NCI

FYSA

From: Sharpless, Norman (NIH/NCI) [E] <norman.sharpless@nih.gov>
Date: April 15, 2020 at 2:52:16 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>, Lowy, Douglas R (NIH) <lowyd@mail.nih.gov>
Subject: FW: Devices received by NCI

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/15/2020 5:08:24 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: Senator Blunt and Senator Alexander call

Would be happy to do so. [REDACTED] (b) (5)

Thanks
Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 15, 2020 at 4:37:11 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Senator Blunt and Senator Alexander call

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/15/2020 1:10:16 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Saliva test? EUA?

Have follow up for you

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 14, 2020 at 5:29:56 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: RE: Saliva test? EUA?

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/15/2020 1:56:41 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: (b) (5)

Nicely categorized but what should be the next steps?

From: Kratsios, Michael J. EOP/OSTP (b) (6)@ostp.eop.gov>
Date: April 15, 2020 at 8:52:58 AM EDT
To: Liddell, Christopher P. EOP/WHO (b) (6)who.eop.gov>, Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Kushner, Jared C. EOP/WHO <jck@who.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Seema Verma <(b) (6)cms.hhs.gov>, Sharpless, Norman E (NIH) <norman.sharpless@nih.gov>, Tromberg, Bruce J (NIH) <bruce.tromberg@nih.gov>, Collins, Francis S (NIH) <collinsf@od.nih.gov>, Butterfield, Nicholas W. EOP/WHO <(b) (6)who.eop.gov>, Droegemeier, Kelvin K. EOP/OSTP <(b) (6)ostp.eop.gov>
Subject: RE: (b) (5)

From: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Sent: 3/30/2020 7:59:49 AM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9d983419fcd-HHS-olx1-cd]; [REDACTED]@cms.hhs.gov; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Good-Cohn, Meredith (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e06154b83bb4cb8a7b01816905e1300-HHS-Meredit]
Subject: Operational Check-in
Location: Roosevelt Room
Start: 3/31/2020 2:30:00 PM
End: 3/31/2020 3:00:00 PM
Show Time As: Tentative
Recurrence: (none)

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/14/2020 5:13:06 PM
To: Liddell, Christopher P. EOP/WHO [REDACTED] (b) (6) who.eop.gov]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS- (b) (6) Kratsios, Michael J. EOP/OSTP [Michael.J.Kratsios@ostp.eop.gov]
CC: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Kushner, Jared C. EOP/WHO [jck@who.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Seema Verma [REDACTED] (b) (6) @cms.hhs.gov]; Sharpless, Norman E (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d860d490594f4675960aad587639ed9c-HHS-norman.]; Tromberg, Bruce J (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5089fb4d6fa44f82bea7b1016d4d4d5d-HHS-bruce.t]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Butterfield, Nicholas W. EOP/WHO [REDACTED] (b) (6) who.eop.gov]; Droegemeier, Kelvin K. EOP/OSTP [REDACTED] (b) (6) ostp.eop.gov]
Subject: RE: [REDACTED] (b) (5)

Michael,

[REDACTED] (b) (5)? I am happy to facilitate.
Steve

From: Liddell, Christopher P. EOP/WHO <[REDACTED] (b) (6) who.eop.gov>
Date: April 14, 2020 at 5:11:38 PM EDT
To: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, Fauci, Anthony S (NIH) <[REDACTED] (b) (6) niaid.nih.gov>, Kratsios, Michael J. EOP/OSTP <Michael.J.Kratsios@ostp.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Kushner, Jared C. EOP/WHO <jck@who.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Seema Verma <[REDACTED] (b) (6) cms.hhs.gov>, Sharpless, Norman E (NIH) <norman.sharpless@nih.gov>, Tromberg, Bruce J (NIH) <bruce.tromberg@nih.gov>, Collins, Francis S (NIH) <collinsf@od.nih.gov>, Butterfield, Nicholas W. EOP/WHO <[REDACTED] (b) (6) who.eop.gov>, Droegemeier, Kelvin K. EOP/OSTP <[REDACTED] (b) (6) ostp.eop.gov>
Subject: RE: [REDACTED] (b) (5)

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/14/2020 6:51:47 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Debi Birx MD [Deborah.L.Birx@nsc.eop.gov]; Jared Kushner [Jck@who.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Joe Grogan [Joseph.J.Grogan@who.eop.gov]; Seema Verma [sv1@cms.hhs.gov]
CC: Sharpless, Norman E (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d860d490594f4675960aad587639ed9c-HHS-norman.]; Tromberg, Bruce J (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5089fb4d6fa44f82bea7b1016d4d4d5d-HHS-bruce.t]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]
Subject: RE: (b) (5)

Thanks, Tony. (b) (5)
Steve

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>
Date: April 13, 2020 at 10:08:28 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Debi Birx MD <Deborah.L.Birx@nsc.eop.gov>, Jared Kushner <Jck@who.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Joe Grogan <Joseph.J.Grogan@who.eop.gov>, Seema Verma <(b) (6)cms.hhs.gov>
Cc: Sharpless, Norman E (NIH) <norman.sharpless@nih.gov>, Tromberg, Bruce J (NIH) <bruce.tromberg@nih.gov>, Collins, Francis S (NIH) <collinsf@od.nih.gov>
Subject: RE: (b) (5)

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/14/2020 9:12:55 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
CC: Tyler Ann McGuffee [Tyler.A.McGuffee2@ovp.eop.gov]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: [REDACTED] (b) (5)

Debi,

Follow up for you re: the Abbott meeting. They completely understood your point about the usage of the PoC serology test.

The CEO wanted me to pass along that the sensitivity/specificity information they gave us was a composite of IgG and IgM. [REDACTED] (b) (4) [REDACTED] (b) (5)
[REDACTED]

I also had a conversation with them about manufacturing ramp up and there is some flexibility. [REDACTED] (b) (5)
[REDACTED]

Thanks
Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 14, 2020 at 6:56:23 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Fauci, Anthony S (NIH) <[REDACTED] (b) (6)niaid.nih.gov>, Kushner, Jared C. EOP/WHO <jck@who.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, Seema Verma <[REDACTED] (b) (6)cms.hhs.gov>, Sharpless, Norman E (NIH) <norman.sharpless@nih.gov>, Tromberg, Bruce J (NIH) <bruce.tromberg@nih.gov>, Collins, Francis S (NIH) <collinsf@od.nih.gov>
Subject: Re: [REDACTED] (b) (5)

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/13/2020 8:24:39 AM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: [REDACTED] (b) (5)

Joe,
Thank you. [REDACTED] (b) (5)? Keagan, let's talk.
Steve

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: April 13, 2020 at 8:23:50 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: [REDACTED] (b) (5)

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/13/2020 7:55:44 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: Working on testing strategy

We talked about #1 last Thursday at the pre-task force meeting. Do you need me to follow up in any way?
S

From: Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>
Date: April 12, 2020 at 1:43:20 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Working on testing strategy

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/12/2020 11:22:42 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
Subject: Fwd: Retail Infographic - Best Practices for Retail During the COVID-19 Pandemic

For your information. We created this for our regulated food industry.
Steve

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Date: April 11, 2020 at 11:19:56 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Retail Infographic - Best Practices for Retail During the COVID-19 Pandemic

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/9/2020 5:36:10 PM
To: Frank.Olivarria@fda.hhs.gov
Subject: ALS Check-In
Attachments: Tentative: ALS Check-In

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/9/2020 8:02:42 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Seema Verma [Seema.Verma.OA@cms.hhs.gov]
CC: Polowczyk, John P RADM USN JS J4 (USA) [john.p.polowczyk.mil@mail.mil]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Subject: Re: Excellent call with the lab directors

Deb,
We are very happy to have a call with them. Who is their point of contact and we will arrange?
Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 8, 2020 at 9:40:50 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Seema Verma <Seema.Verma.OA@cms.hhs.gov>
Cc: Polowczyk, John P RADM USN JS J4 (USA) <john.p.polowczyk.mil@mail.mil>, Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Subject: Excellent call with the lab directors

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/13/2020 7:45:22 AM
To: Wainer, Andrea F [andrea.wainer@abbott.com]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Haddad, Carla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8627be6986b64424883e696551c54187-HHS-Carla.H]; Deborah Birx (deborah.l.birx@nsc.eop.gov) [deborah.l.birx@nsc.eop.gov]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Ford, Robert B [Robert.Ford@abbott.com]
Subject: Re: Abbott's Covid Data

Thank you, Andrea.
Steve

From: Wainer, Andrea F <andrea.wainer@abbott.com>
Date: April 12, 2020 at 6:37:18 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Haddad, Carla (OS) <Carla.Haddad@hhs.gov>, Deborah Birx (deborah.l.birx@nsc.eop.gov) <deborah.l.birx@nsc.eop.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Ford, Robert B <Robert.Ford@abbott.com>
Subject: Abbott's Covid Data

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/8/2020 9:51:00 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: Serology testing -CONFIDENTIAL AND PREDECISIONAL

FYI

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: April 8, 2020 at 9:49:31 AM EDT
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Serology testing -CONFIDENTIAL AND PREDECISIONAL

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/8/2020 8:28:47 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
CC: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
Subject: Re: 4/7 IGA Governor Press Conference Tracker

Ok

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 8, 2020 at 8:28:13 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Subject: Re: 4/7 IGA Governor Press Conference Tracker

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/12/2020 5:07:20 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: [REDACTED] (b) (5)

Perhaps we can discuss?

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 12, 2020 at 12:54:00 PM EDT
To: Sharpless, Norman E (NIH) <norman.sharpless@nih.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: [REDACTED] (b) (5)

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/12/2020 5:06:12 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Finally read the packet insert

I did. Our approvals are dependent upon which company is able to provide the validation data. Obviously,

(b) (5)

S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 12, 2020 at 3:40:58 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Finally read the packet insert

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/12/2020 5:05:17 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Working on testing strategy

Deb,
This is good.

Some minor comments - [REDACTED] (b) (5)

[REDACTED]

[REDACTED] (b) (5)

[REDACTED]

Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 12, 2020 at 4:49:22 PM EDT
To: Fauci, Anthony S (NIH) <(b) (6)@niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>
Subject: Re: Working on testing strategy

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/12/2020 4:55:45 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: [REDACTED] (b) (5)

We definitely need some help here.

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 12, 2020 at 2:28:00 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Sharpless, Norman E (NIH) <norman.sharpless@nih.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: [REDACTED] (b) (5)

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/7/2020 5:57:38 PM
To: Short, Marc T. EOP/OVP [Marc.T.Short@ovp.eop.gov]; Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: [REDACTED] (b) (5)

FYSA

[REDACTED] (b) (5)

[REDACTED] ?

Steve

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 7, 2020 at 5:20:56 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Subject: [REDACTED] (b) (5)

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/8/2020 8:26:59 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
CC: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: Re: 4/7 IGA Governor Press Conference Tracker

They want our advice and want to scale up. Are you free for a quick call?
S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 8, 2020 at 8:24:59 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: 4/7 IGA Governor Press Conference Tracker

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/8/2020 9:15:15 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Serology Question Follow Up - BD

For the top of your inbox.

(b) (4).

Thanks, Joe

From: Dave Hickey <Dave_Hickey@bd.com>
Date: April 6, 2020 at 9:31:04 PM EDT
To: Whitaker, Scott <SWhitaker@AdvaMed.org>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Serology Question Follow Up - BD

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/7/2020 9:47:27 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Serology Surveillance

Do we have a list of these groups who have developed LDT serology tests already?

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 1, 2020 at 11:57:57 AM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Watson, Ian D. EOP/OSTP (b) (6)@ostp.eop.gov>
Cc: Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Serology Surveillance

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/8/2020 8:24:56 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: [EXTERNAL] ...

Wanted you to be aware of this. I spoke to the health officials at NY State and there is no randomized trial and there is no placebo.

Steve

From: Bauer, Zachary C. EOP/OVP [REDACTED] (b) (5)@ovp.eop.gov>
Date: April 7, 2020 at 5:55:17 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: [EXTERNAL] ...

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/6/2020 12:02:41 PM
To: Staff Secretary (b) (6)@who.eop.gov; DL Chief of Staff Office (b) (6)@WHO.eop.gov; Salvi, Mary E. EOP/WHO (b) (6)@who.eop.gov; Eisenberg, John A. EOP/WHO (b) (6)@who.eop.gov; Philbin, Patrick F. EOP/WHO (b) (6)@who.eop.gov; (b) (6)@who.eop.gov; Kushner, Jared C. EOP/WHO [jck@who.eop.gov]; Berkowitz, Avraham J. EOP/WHO (b) (6)@who.eop.gov; Hicks, Hope C. EOP/WHO [Hope@who.eop.gov]; Vought, Russell T. EOP/OMB (b) (6)@omb.eop.gov; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Pottinger, Matthew F. EOP/WHO (b) (6)@who.eop.gov; john.gountanis@hq.dhs.gov; Blackwell, Juliana [juliana.blackwell@HQ.DHS.GOV]; Ditto, Jessica E. EOP/WHO [Jessica.E.Ditto@who.eop.gov]; Grisham, Stephanie A. EOP/WHO (b) (6)@who.eop.gov; Gidley, Hogan H. EOP/WHO (b) (6)@who.eop.gov; Hahn, Julia A. EOP/WHO (b) (6)@who.eop.gov; Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]; Short, Marc T. EOP/OVP [Marc.T.Short@ovp.eop.gov]; Hoelscher, Douglas L. EOP/WHO (b) (6)@who.eop.gov; Pataki, Tim A. EOP/WHO (b) (6)@who.eop.gov; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS- (b) (6) Ueland, Eric M. EOP/WHO (b) (6)@who.eop.gov; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Liddell, Christopher P. EOP/WHO (b) (6)@who.eop.gov; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Kudlow, Larry A. EOP/WHO (b) (6)@who.eop.gov; Olmem, Andrew J. EOP/WHO (b) (6)@who.eop.gov; Rinat, Ory S. EOP/WHO (b) (6)@who.eop.gov; adam.boehler@dfc.gov; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Conway, Kellyanne E. EOP/WHO [KAC@who.eop.gov]
CC: Staff Secretary (b) (6)@who.eop.gov
Subject: RE: FOR QUICK REVIEW: POTUS Remarks for Call with pharmaceutical industry CEOs

Look good to me. Thanks
Steve

From: Staff Secretary (b) (6)@who.eop.gov
Date: April 6, 2020 at 11:52:34 AM EDT
To: DL Chief of Staff Office (b) (6)@WHO.eop.gov, Salvi, Mary E. EOP/WHO (b) (6)@who.eop.gov, Eisenberg, John A. EOP/WHO (b) (6)@who.eop.gov, Philbin, Patrick F. EOP/WHO (b) (6)@who.eop.gov, imt@who.eop.gov (b) (6)@who.eop.gov, Kushner, Jared C. EOP/WHO <jck@who.eop.gov>, Berkowitz, Avraham J. EOP/WHO (b) (6)@who.eop.gov, Hicks, Hope C. EOP/WHO <Hope@who.eop.gov>, Vought, Russell T. EOP/OMB (b) (6)@omb.eop.gov, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>, Pottinger, Matthew F. EOP/WHO (b) (6)@who.eop.gov, john.gountanis@hq.dhs.gov <john.gountanis@hq.dhs.gov>, Blackwell, Juliana <juliana.blackwell@HQ.DHS.GOV>, Ditto, Jessica E. EOP/WHO (b) (6)@who.eop.gov, Grisham, Stephanie A. EOP/WHO (b) (6)@who.eop.gov, Gidley, Hogan H. EOP/WHO (b) (6)@who.eop.gov, Hahn, Julia A. EOP/WHO (b) (6)@who.eop.gov, Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>, Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>, Hoelscher, Douglas L. EOP/WHO (b) (6)@who.eop.gov, Pataki, Tim A. EOP/WHO (b) (6)@who.eop.gov, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Ueland, Eric M. EOP/WHO (b) (6)@who.eop.gov, Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, Liddell, Christopher P. EOP/WHO (b) (6)@who.eop.gov, Harrison, Brian (OS) <Brian.Harrison@hhs.gov>, Kudlow, Larry A. EOP/WHO (b) (6)@who.eop.gov, Olmem, Andrew J. EOP/WHO (b) (6)@who.eop.gov, Rinat, Ory S. EOP/WHO <Ory.S.Rinat@who.eop.gov>, adam.boehler@dfc.gov <adam.boehler@dfc.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Conway, Kellyanne

FDA-OC-2020-2523-000598

HHS-FDA-20-0498-D-000115

E. EOP/WHO <KAC@who.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>

Cc: Staff Secretary [REDACTED] (b) (6)@who.eop.gov>

Subject: RE: FOR QUICK REVIEW: POTUS Remarks for Call with pharmaceutical industry CEOs

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/6/2020 2:36:24 PM
To: Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Testing Partnership Expansion Soft/Pre Launch

I've heard about this from Brett but I don't believe the task force has received a briefing. Deb, I do have additional positive info re: serology testing for your situational awareness.

Thanks

S

From: Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>
Date: April 5, 2020 at 8:54:18 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: Testing Partnership Expansion Soft/Pre Launch

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/7/2020 8:31:34 AM
To: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS (b) (6)]
Subject: FW: COVID 19 Rx Options as of Mar 19 2020.pdf

I thought you all might want to see this URL related to therapies.
thanks
Steve

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Date: April 3, 2020 at 12:57:28 PM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: FW: COVID 19 Rx Options as of Mar 19 2020.pdf

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/7/2020 6:21:41 PM
To: Short, Marc T. EOP/OVP [Marc.T.Short@ovp.eop.gov]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Subject: [REDACTED] (b) (5)

Will do

From: Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>
Date: April 7, 2020 at 6:20:38 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Subject: [REDACTED] (b) (5)

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/7/2020 5:15:15 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
CC: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9d983419fcd-HHS-olx1-cd]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS- (b) (6)]
Subject: Re: Haines masks

Ok thx

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 7, 2020 at 5:14:11 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>
Subject: Re: Haines masks

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/5/2020 9:14:05 AM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
CC: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Tammy Beckham????

I spoke to Brett and we are going to limit contacts with Abbott to allow them to get their work done. FYSA, Jeff and I have a call with them tomorrow to go over the technical details of their development. More to come
S

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: April 5, 2020 at 9:06:52 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Subject: Re: Tammy Beckham????

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/8/2020 8:21:33 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (5) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: FW: 4/7 IGA Governor Press Conference Tracker

I'm sure you are aware of NYS' desire to talk to us about serology testing and their plan to return to work. Deb, (b) (5) Howard Zucker from NYS is supposed to call me today.
Steve

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: April 7, 2020 at 12:10:14 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: FW: 4/7 IGA Governor Press Conference Tracker

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/6/2020 5:37:31 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: [REDACTED] (b) (5)

Thanks. [REDACTED] (b) (5)
S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 6, 2020 at 5:35:58 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re [REDACTED] (b) (5)

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/6/2020 5:37:01 PM
To: CMS SV1 (b) (6) cms.hhs.gov]; Good-Cohn, Meredith (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e06154b83bb4cb8a7b01816905e1300-HHS-Meredith]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Joe Grogan [Joseph.J.Grogan@who.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9d983419fcd-HHS-olx1-cd]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Call with serology test CEOs

Thanks, Seema

From: CMS (b) (6) <(b) (6) cms.hhs.gov>
Date: April 6, 2020 at 5:34:26 PM EDT
To: Good-Cohn, Meredith (CMS) <Meredith.Good-Cohn@cms.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Adams, Jerome (OS) <Jerome.Adams@hhs.gov>, Debi Birx <Deborah.L.Birx@nsc.eop.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Fauci, Anthony S (NIH) <(b) (6) niaid.nih.gov>, Joe Grogan <Joseph.J.Grogan@who.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Call with serology test CEOs

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/2/2020 4:39:04 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
Subject: Fwd: First coronavirus blood test gets FDA emergency authorization

From: POLITICO Pro <politicoemail@politicopro.com>
Date: April 2, 2020 at 1:23:31 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: First coronavirus blood test gets FDA emergency authorization

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/6/2020 1:35:54 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fw: Journal publisher raises red flags about French malaria drug study

FYI

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Date: April 6, 2020 at 1:33:04 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Fw: Journal publisher raises red flags about French malaria drug study

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/5/2020 9:00:15 AM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Tammy Beckham????

I definitely know who this is. I'll check with Brett.
Steve

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: April 4, 2020 at 8:48:03 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Tammy Beckham????

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/2/2020 4:38:49 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: First coronavirus blood test gets FDA emergency authorization

From: POLITICO Pro <politicoemail@politicopro.com>
Date: April 2, 2020 at 1:23:31 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: First coronavirus blood test gets FDA emergency authorization

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/7/2020 8:24:57 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Serology Question Follow Up - BD

As per our discussion, this issue regarding the Chinese export ban was flagged by the President of BD.

[REDACTED] (b) (5)

[REDACTED].

[REDACTED] (b) (5).

Thanks
Steve

From: Whitaker, Scott <SWhitaker@AdvaMed.org>
Date: April 6, 2020 at 9:25:55 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Hickey, David <Dave.Hickey@bd.com>
Subject: Fwd: Serology Question Follow Up - BD

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/6/2020 1:35:12 PM
To: Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (5) Joe Grogan [Joseph.J.Grogan@who.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Call with serology test CEOs

good point, Jerome. NIH/CDC are validating some tests and the commercial manufacturers intend to go through the EUA process (b) (5)

Steve

From: Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>
Date: April 6, 2020 at 1:08:18 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Debi Birx <Deborah.L.Birx@nsc.eop.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Joe Grogan <Joseph.J.Grogan@who.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Call with serology test CEOs

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/7/2020 7:47:02 AM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: Question

I'll check although I do know that there is a ton of variability.

S

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: April 7, 2020 at 7:46:26 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: Question

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/6/2020 5:29:24 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: (b) (5)

FYSA

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 3, 2020 at 1:16:36 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>
Subject: RE: (b) (5)

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/7/2020 9:08:13 AM
To: Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Conway, Kellyanne E. EOP/WHO [KAC@who.eop.gov]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hicks, Hope C. EOP/WHO [Hope@who.eop.gov]; Rinat, Ory S. EOP/WHO [Ory.S.Rinat@who.eop.gov]; Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]
Subject: Re: Convalescent plasma program

Completely agree, Katie.

From: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Date: April 7, 2020 at 9:07:13 AM EDT
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Conway, Kellyanne E. EOP/WHO <KAC@who.eop.gov>, Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hicks, Hope C. EOP/WHO <Hope@who.eop.gov>, Rinat, Ory S. EOP/WHO <Ory.S.Rinat@who.eop.gov>, Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>
Subject: Re: Convalescent plasma program

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/7/2020 8:21:23 AM
To: Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]
CC: Conway, Kellyanne E. EOP/WHO [KAC@who.eop.gov]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Hicks, Hope C. EOP/WHO [Hope@who.eop.gov]; Rinat, Ory S. EOP/WHO [Ory.S.Rinat@who.eop.gov]; Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]
Subject: Re: Convalescent plasma program

(b) (5)

Thanks
Steve

From: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Date: April 7, 2020 at 8:18:56 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Conway, Kellyanne E. EOP/WHO <KAC@who.eop.gov>, Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Hicks, Hope C. EOP/WHO <Hope@who.eop.gov>, Rinat, Ory S. EOP/WHO <Ory.S.Rinat@who.eop.gov>, Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>
Subject: Re: Convalescent plasma program

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/7/2020 7:44:56 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Question

FYSA

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: April 6, 2020 at 7:52:46 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Question

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/6/2020 10:41:05 AM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Staff Secretary (b) (6)@who.eop.gov; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
CC: Campana, Alexandra D. EOP/WHO (b) (6)@who.eop.gov; Troutman, Joel D. EOP/WHO (b) (6)@who.eop.gov; Pataki, Tim A. EOP/WHO (b) (6)@who.eop.gov; Williams, Michael B. EOP/WHO (b) (6)@who.eop.gov
Subject: Re: FOR QUICK REVIEW: POTUS Remarks for Call with pharmaceutical industry CEOs

That is correct Joe

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: April 6, 2020 at 10:20:38 AM EDT
To: Staff Secretary (b) (6)@who.eop.gov, Rom, Colin <Colin.Rom@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Campana, Alexandra D. EOP/WHO <(b) (6)@who.eop.gov>, Troutman, Joel D. EOP/WHO (b) (6)@who.eop.gov, Pataki, Tim A. EOP/WHO (b) (6)@who.eop.gov, Williams, Michael B. EOP/WHO (b) (6)@who.eop.gov
Subject: Re: FOR QUICK REVIEW: POTUS Remarks for Call with pharmaceutical industry CEOs

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/6/2020 12:06:24 PM
To: Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Deborah.L.Birx@nsc.eop.gov; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]
CC: marc.t.short@ovp.eop.gov
Subject: Re: Discussion with Montana, Idaho, NH, VT

Thanks, Jerome. This is really helpful.
Steve

From: Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>
Date: April 6, 2020 at 10:57:10 AM EDT
To: Deborah.L.Birx@nsc.eop.gov <Deborah.L.Birx@nsc.eop.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: marc.t.short@ovp.eop.gov <marc.t.short@ovp.eop.gov>
Subject: Discussion with Montana, Idaho, NH, VT

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/3/2020 11:59:24 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: A victory! New sanitizer supplies coming nationwide. Thank you. Question on donation?

From: Hayden, Lou <lou.hayden@lowes.com>
Date: April 3, 2020 at 11:33:19 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: Russo, Joseph H. EOP/WHO (b) (6)@who.eop.gov>, Tim Pataki (b) (6)@who.eop.gov>
Subject: A victory! New sanitizer supplies coming nationwide. Thank you. Question on donation?

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/4/2020 8:42:17 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Hydroxychloroquine

Joe,
FYI. Do you have time for a call this morning?
Steve

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHPSE) <zud4@cdc.gov>
Date: April 3, 2020 at 5:15:31 PM EDT
To: Schuchat, Anne (CDC) <acs1@cdc.gov>, Messonnier, Nancy E (CDC) <nar5@cdc.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Brooks, John T (CDC) <zud4@cdc.gov>
Subject: RE: Hydroxychloroquine

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/27/2020 7:06:45 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: For our 7:45 am call: Draft March 27 2020 Commissioner CTAP TP.docx
Attachments: Draft March 27 2020 Commissioner CTAP TP.docx

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/15/2020 1:10:09 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Saliva test? EUA?

Have follow up for you

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 14, 2020 at 5:29:56 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: RE: Saliva test? EUA?

Rutgers LDT, for which they had previously notified us that they were testing patient specimens, uses saliva as a specimen type. They have been included under the LDT umbrella EUA. Their authorization limits the collection of saliva to a healthcare setting and their results aren't transferable to other tests at the present time. (b) (4)

Hence, why the use of saliva is limited to just their test.

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Tuesday, April 14, 2020 5:22 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>
Subject: Saliva test? EUA?

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/30/2020 7:56:20 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Need the CTAP graphics for my call with Joe Grogan at 7:45

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: March 30, 2020 at 7:09:38 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Need the CTAP graphics for my call with Joe Grogan at 7:45

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/30/2020 7:54:20 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Need the CTAP graphics for my call with Joe Grogan at 7:45

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: March 30, 2020 at 7:09:38 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Need the CTAP graphics for my call with Joe Grogan at 7:45

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/30/2020 7:27:46 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Need the CTAP graphics for my call with Joe Grogan at 7:45

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: March 30, 2020 at 7:09:38 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Need the CTAP graphics for my call with Joe Grogan at 7:45

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/26/2020 9:36:16 AM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Campana, Alexandra D. EOP/WHO [Alexandra.D.Campana2@who.eop.gov]
Subject: Re: Task Force today -- convalescent plasma

Yes. Keagan and I are working on it
Thx
S

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: March 26, 2020 at 9:13:54 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Campana, Alexandra D. EOP/WHO <Alexandra.D.Campana2@who.eop.gov>
Subject: Task Force today -- convalescent plasma
Importance: High

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/26/2020 8:11:29 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Did Abbott file on its Alere platform

Yes, for sure

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 26, 2020 at 7:50:09 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Did Abbott file on its Alere platform

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/26/2020 7:30:59 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Did Abbott file on its Alere platform

They tell us today

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 26, 2020 at 5:55:36 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Did Abbott file on its Alere platform

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/25/2020 6:11:11 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffb9d983419fcd-HHS-olx1-cd]
Subject: RE: CORONAVIRUS FLAG: UK to make 15-minute at-home kits available within days

I'll let Bob and Deb respond from a public health point of view. An antibody test is essential for detecting high titers that will enable both convalescent plasma and hyperimmune globulin. (b) (5).
S

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: March 25, 2020 at 5:57:48 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: RE: CORONAVIRUS FLAG: UK to make 15-minute at-home kits available within days

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/25/2020 8:27:04 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: CORONAVIRUS FLAG: UK to make 15-minute at-home kits available within days

(b) (4), (b) (5)

S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 25, 2020 at 8:24:31 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: CORONAVIRUS FLAG: UK to make 15-minute at-home kits available within days

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/25/2020 1:23:24 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Bonner, Maria K. EOP/WHO (b) (6)@who.eop.gov; Campana, Alexandra D. EOP/WHO (b) (6)@who.eop.gov
Subject: Re: Tps on Gilead expanded access

Yes, we need to revisit. Have additional updates on therapeutics for you Joe

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 25, 2020 at 9:19:13 AM EDT
To: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Bonner, Maria K. EOP/WHO (b) (6)@who.eop.gov, Campana, Alexandra D. EOP/WHO (b) (6)@who.eop.gov
Subject: Re: Tps on Gilead expanded access

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/24/2020 8:28:07 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: CVS Action on Potentially Short Supply Drugs

FYI

From: Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>
Date: March 24, 2020 at 8:25:04 PM EDT
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: CVS Action on Potentially Short Supply Drugs

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/25/2020 4:00:43 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: Re: CORONAVIRUS FLAG: UK to make 15-minute at-home kits available within days

(b) (5)

One other thing. The test Mr. Martin refers to appears to be an antibody test not a diagnostic test for COVID-19. It's important to know that under the recent guidance companies can notify us that they are entering the market but we do not have scientific insight into how the tests perform. We have been working with other companies to expedite antibody testing.

We are very happy to provide additional information as well as technical assistance to anyone wishing to purchase these tests.

Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 25, 2020 at 2:46:32 PM EDT
To: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: CORONAVIRUS FLAG: UK to make 15-minute at-home kits available within days

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/24/2020 6:39:55 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Subject: Re: GA sterigenics plant?

Joe,
We had a call with Governor Kemp today. This is in the hands of the County. (b) (5)
(b) (5) Glad to discuss further.
Steve

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: March 20, 2020 at 6:05:28 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Bonner, Maria K. EOP/WHO (b) (6)@who.eop.gov, Campana, Alexandra D. EOP/WHO (b) (6)@who.eop.gov
Subject: GA sterigenics plant?

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/24/2020 6:31:07 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Summary of clinician feedback

Clinician feedback on the Oracle system

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Date: March 24, 2020 at 9:30:07 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: Summary of clinician feedback

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/24/2020 6:28:58 PM
To: Wainer, Andrea F [andrea.wainer@abbott.com]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
CC: Ford, Robert B [Robert.Ford@abbott.com]
Subject: RE: [EXTERNAL] Re: Abbott Update

Thanks, Andrea.

Steve

From: Wainer, Andrea F <andrea.wainer@abbott.com>
Date: March 24, 2020 at 6:12:22 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Ford, Robert B <Robert.Ford@abbott.com>
Subject: RE: [EXTERNAL] Re: Abbott Update

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/24/2020 6:26:54 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Bonner, Maria K. EOP/WHO [Maria.K.Bonner@who.eop.gov]; Campana, Alexandra D. EOP/WHO [REDACTED] (b) (6)@who.eop.gov]
Subject: Re: Talkers on CTAP

Totally agree about past tense. Thanks, Joe. We'll work on this.
Steve

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: March 24, 2020 at 6:26:03 PM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Bonner, Maria K. EOP/WHO [REDACTED] (b) (6)@who.eop.gov>, Campana, Alexandra D. EOP/WHO [REDACTED] (b) (6)@who.eop.gov>
Subject: Re: Talkers on CTAP

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/24/2020 5:40:23 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: FW: Gilead FDA material

Need to talk to you about this.
S

From: Daniel O'Day <daniel.oday@gilead.com>
Date: March 23, 2020 at 3:48:06 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Subject: FW: Gilead FDA material

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/24/2020 5:23:24 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: FDA encourages use of experimental coronavirus treatment made from survivors' blood

This is really good work.

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Date: March 24, 2020 at 5:09:53 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: FDA encourages use of experimental coronavirus treatment made from survivors' blood

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/25/2020 2:16:43 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Campana, Alexandra D. EOP/WHO (b) (6)@who.eop.gov
Subject: RE: Ban on gay men's blood donations

KEagan,
When will this new guidance be done? I think it is going through clearance.
S

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Date: March 25, 2020 at 2:10:19 PM EDT
To: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Campana, Alexandra D. EOP/WHO (b) (6)@who.eop.gov
Subject: RE: Ban on gay men's blood donations

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/25/2020 12:38:40 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: When can you present CTAP to the TF?

Yes, pre-brief Thursday. Colin can you make sure that happens?

S

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: March 25, 2020 at 11:52:38 AM EDT
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: When can you present CTAP to the TF?

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/25/2020 12:32:30 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: FDA presentation friday

Joe,
It's coronavirus treatment acceleration plan

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: March 25, 2020 at 12:22:22 PM EDT
To: Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>, Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>, Miller, Stephen EOP/WHO <Stephen.Miller@who.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: FDA presentation friday

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/24/2020 5:03:28 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: FW: Gilead FDA material

From: Daniel O'Day <daniel.oday@gilead.com>
Date: March 23, 2020 at 3:48:06 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Subject: FW: Gilead FDA material

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/25/2020 9:39:52 AM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: STATE FLAG: Nevada governor bans malaria drugs for coronavirus patients

That is very interesting. This is definitely a patient-doctor issue within a local (state) context.

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: March 25, 2020 at 9:34:51 AM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: STATE FLAG: Nevada governor bans malaria drugs for coronavirus patients

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/24/2020 4:39:36 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: [EXTERNAL] URGENT: Significantly More Viable Coronavirus Test Kits - Made in USA

(b) (4)

S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 23, 2020 at 8:59:27 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: [EXTERNAL] URGENT: Significantly More Viable Coronavirus Test Kits - Made in USA

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/24/2020 4:20:24 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Ford, Robert B [Robert.Ford@abbott.com]
CC: Wainer, Andrea F [andrea.wainer@abbott.com]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
Subject: RE: [EXTERNAL] Re: Abbott Update

Robert,
Terrific work. Thank you.
Steve

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: March 24, 2020 at 3:03:26 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Ford, Robert B <Robert.Ford@abbott.com>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Wainer, Andrea F <andrea.wainer@abbott.com>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: RE: [EXTERNAL] Re: Abbott Update

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/24/2020 9:14:48 AM
To: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Debi Birx [Deborah.L.Birx@nsc.eop.gov]
CC: McGuffee, Tyler A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: Follow up on Oracle Platform and therapeutics for COVID-19

Thanks, Bob.

From: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Date: March 24, 2020 at 9:09:57 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Debi Birx <Deborah.L.Birx@nsc.eop.gov>
Cc: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: Follow up on Oracle Platform and therapeutics for COVID-19

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/23/2020 2:20:59 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6)]
CC: Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: Quick Review: Press Conference Open - March 23

Good point. We'll revise. Looks like this won't be announced this evening.
S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 23, 2020 at 10:31:46 AM EDT
To: Fauci, Anthony S (NIH) <(b) (6)@niaid.nih.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lane, Henry C (NIH) <clane@niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: Quick Review: Press Conference Open - March 23

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/22/2020 4:00:20 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; CMS SV1 (b) (6) cms.hhs.gov
CC: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf6245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Liddell, Christopher P. EOP/WHO (b) (6) who.eop.gov
Subject: Re: Oracle Platform

Thanks, Chris. Please let me know if you have any questions.
Steve

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: March 21, 2020 at 7:29:35 PM EDT
To: CMS (b) (6) <(b) (6) cms.hhs.gov>
Cc: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Fauci, Anthony S (NIH) <(b) (6) niaid.nih.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Brookes, Brady (CMS) <Brady.Brookes@cms.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>, Lane, Henry C (NIH) <clane@niaid.nih.gov>, Collins, Francis S (NIH) <collinsf@od.nih.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Liddell, Christopher P. EOP/WHO <(b) (6) who.eop.gov>
Subject: Re: Oracle Platform

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/22/2020 3:56:32 PM
To: CMS SV1 (b) (6) cms.hhs.gov; 'Grogan, Joseph J. EOP/WHO' [Joseph.J.Grogan@who.eop.gov]
CC: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Liddell, Christopher P. EOP/WHO (b) (6) who.eop.gov
Subject: RE: Oracle Platform

Thanks, Seema.

From: CMS (b) (6) (b) (6) cms.hhs.gov
Date: March 21, 2020 at 8:54:23 PM EDT
To: 'Grogan, Joseph J. EOP/WHO' <Joseph.J.Grogan@who.eop.gov>
Cc: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Fauci, Anthony S (NIH) <(b) (6) niaid.nih.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Brookes, Brady (CMS) <Brady.Brookes@cms.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>, Lane, Henry C (NIH) <clane@niaid.nih.gov>, Collins, Francis S (NIH) <collinsf@od.nih.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Liddell, Christopher P. EOP/WHO (b) (6) who.eop.gov
Subject: RE: Oracle Platform

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/23/2020 6:47:31 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: Gilead FDA material

Thoughts? Let me know when you're free for a call.

Thanks

S

From: Daniel O'Day <daniel.oday@gilead.com>
Date: March 22, 2020 at 10:39:25 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Gilead FDA material

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/22/2020 3:50:51 PM
To: McGuffee, Tyler A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: Post-Call Report/Summary on FDA/Phoenix Biotechnology INC Call

Tyler,

(b) (5)

Steve

From: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Date: March 22, 2020 at 2:41:18 AM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Post-Call Report/Summary on FDA/Phoenix Biotechnology INC Call

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/23/2020 10:04:33 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Quick Review: Press Conference Open - March 23

(b) (5)

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>
Date: March 23, 2020 at 9:03:21 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: FW: Quick Review: Press Conference Open - March 23

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/23/2020 8:59:54 AM
To: Liddell, Christopher P. EOP/WHO [(b) (6) who.eop.gov]
CC: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; CMS SV1 [(b) (6) cms.hhs.gov]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]
Subject: Re: Oracle Platform

Chris,
Amy is working on this in real time. We'll get this to you.
Steve

From: Liddell, Christopher P. EOP/WHO <(b) (6) who.eop.gov>
Date: March 22, 2020 at 5:31:29 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, CMS (b) (6) <(b) (6) cms.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Fauci, Anthony S (NIH) <(b) (6) niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Brookes, Brady (CMS) <Brady.Brookes@cms.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>, Lane, Henry C (NIH) <clane@niaid.nih.gov>, Collins, Francis S (NIH) <collinsf@od.nih.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Subject: Re: Oracle Platform

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/22/2020 3:35:06 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Short, Marc T. EOP/OVP [Marc.T.Short@ovp.eop.gov];
Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; AMA2@HHS.GOV;
Seema Verma [Seema.Verma.OA@cms.hhs.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd];
Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]
CC: McGuffee, Tyler A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Hurst, Natalie R. EOP/OVP
[REDACTED] (b) (6)@ovp.eop.gov; Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]
Subject: Re: Birx virtual 22 March 2020

Deb,
Thank you very much for the information, your caution, and please take care.
Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 22, 2020 at 8:29:18 AM EDT
To: Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>, Fauci, Anthony S (NIH) <[REDACTED] (b) (6)niaid.nih.gov>,
Hahn, Stephen <SH1@fda.hhs.gov>, AMA2@HHS.GOV <AMA2@HHS.GOV>, Seema Verma
<Seema.Verma.OA@cms.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Adams, Jerome (OS)
<Jerome.Adams@hhs.gov>
Cc: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>, Hurst, Natalie R. EOP/OVP
[REDACTED] (b) (6)@ovp.eop.gov, Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>
Subject: Birx virtual 22 March 2020

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/22/2020 3:33:57 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffb983419fcd-HHS-olx1-cd]
Subject: Re: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

(b) (6)

Thanks

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 22, 2020 at 3:33:19 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/22/2020 8:50:41 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; mitchell.katz@nychhc.org
CC: Mary Dale Peterson [M.Peterson@asahq.org]
Subject: Re: [EXTERNAL] re ramping up personnel and ventilators

Mitch

I believe we know each other from time at UCSF.

I've attached the guidance.

Please let me know how we can help.

Steve

<https://www.fda.gov/media/136318/download>

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 22, 2020 at 8:45:38 PM EDT
To: mitchell.katz@nychhc.org <mitchell.katz@nychhc.org>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Mary Dale Peterson <M.Peterson@asahq.org>
Subject: Fwd: [EXTERNAL] re ramping up personnel and ventilators

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/22/2020 11:21:07 AM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: Margolis COVID-19 tx working paper.pdf

Got it

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: March 22, 2020 at 10:55:43 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Margolis COVID-19 tx working paper.pdf

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/22/2020 8:43:31 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; mitchellkatz@NYCHHC.org
CC: Mary Dale Peterson [M.Peterson@asahq.org]
Subject: Re: [EXTERNAL] re ramping up personnel and ventilators

Mitch

I believe we know each other from time at UCSF.

I've attached the guidance.

Please let me know how we can help.

Steve

<https://www.fda.gov/media/136318/download>

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 22, 2020 at 8:38:21 PM EDT
To: mitchellkatz@NYCHHC.org <mitchellkatz@NYCHHC.org>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Mary Dale Peterson <M.Peterson@asahq.org>
Subject: Fwd: [EXTERNAL] re ramping up personnel and ventilators

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/22/2020 3:31:31 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffb983419fcd-HHS-olx1-cd]
Subject: Re: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

Not doing press. I have lots of data on this.

S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 22, 2020 at 3:28:13 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/23/2020 7:11:12 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; McGuffee, Tyler A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
CC: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]
Subject: RE: Genentech and COVID-19

Tony and Deb, (b) (5)
Steve

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>
Date: March 22, 2020 at 6:44:52 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, McGowan, Robert K (CDC) <omc2@cdc.gov>
Subject: RE: Genentech and COVID-19

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/22/2020 3:26:12 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffb983419fcd-HHS-olx1-cd]
Subject: Re: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

We have a good domestic supply of these drugs with the private sector delivering the drugs. We also have imported drug some of which will require regulatory sign off and some of which will not and can enter the usual supply chain. Do you have any time to talk about this?

S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 22, 2020 at 10:28:38 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Fwd: [EXTERNAL] Urgent Oz: Clinical Trial Drug Shortage

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/21/2020 6:25:57 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Hand Sanitizer

FYI if you could help with pro-active situational awareness.
S

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 21, 2020 at 6:22:55 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Hand Sanitizer

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/21/2020 6:22:45 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; McGuffee, Tyler A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
Subject: Fwd: slight revisions for re-clearance

WH cleared if you clear, Deb.

From: Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>
Date: March 21, 2020 at 6:19:54 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: slight revisions for re-clearance

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/21/2020 5:57:06 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: FW: CU portal language EU change 03 21 20 rev-db_HM.docx

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Date: March 21, 2020 at 5:10:28 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>
Subject: FW: CU portal language EU change 03 21 20 rev-db_HM.docx

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/22/2020 4:04:08 PM
To: McGuffee, Tyler A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: Post-Call Report/Summary on FDA/Phoenix Biotechnology INC Call

I believe our group has been actively engaging. Anand, can you help?
thanks

From: McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Date: March 22, 2020 at 4:03:04 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Post-Call Report/Summary on FDA/Phoenix Biotechnology INC Call

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/27/2020 9:39:47 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Hodgson, Christopher M. EOP/OVP
[REDACTED] (b) (5)@ovp.eop.gov]
CC: Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]
Subject: Re: Best person to contact

The company stopped compassionate use but they started an expanded access protocol which we approved on Tuesday. [REDACTED] (b) (5)

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 27, 2020 at 9:04:31 PM EDT
To: Hodgson, Christopher M. EOP/OVP [REDACTED] (b) (4)@ovp.eop.gov>
Cc: Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Best person to contact

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/21/2020 1:55:56 PM
To: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; McGuffee, Tyler A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]
Subject: Re: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

It has it

From: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>
Date: March 21, 2020 at 1:54:45 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Lane, Henry C (NIH) <clane@niaid.nih.gov>, McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, McGowan, Robert K (CDC) <omc2@cdc.gov>
Subject: Re: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/21/2020 12:48:19 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; McGuffee, Tyler A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (5) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]
Subject: Re: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

(b) (5)

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 21, 2020 at 12:40:16 PM EDT
To: Lane, Henry C (NIH) <clane@niaid.nih.gov>, McGuffee, Tyler A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>, Fauci, Anthony S (NIH) <(b) (6) niaid.nih.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, McGowan, Robert K (CDC) <omc2@cdc.gov>
Subject: Re: NEEDS FINAL AFFIRMATIVE CLEARANCE RE: Treatment Document

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/17/2020 8:25:26 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
CC: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS- (b) (6)]
Subject: Re: Chloroquine

Anand
Can you work with CDER on these questions?
S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 17, 2020 at 8:23:40 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Redfield, Robert R (CDC) <olx1@cdc.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>
Subject: Re: Chloroquine

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/21/2020 7:43:17 AM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Gaynor, Pete [pete.gaynor@fema.dhs.gov]
Subject: RE: White House Coronavirus Task Force Meeting

Thx Jeff

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: March 21, 2020 at 7:41:14 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Gaynor, Pete <pete.gaynor@fema.dhs.gov>
Subject: RE: White House Coronavirus Task Force Meeting

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/21/2020 7:32:16 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Gaynor, Pete [pete.gaynor@fema.dhs.gov]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: Re: White House Coronavirus Task Force Meeting

Jeff or Admiral Giroir,
Good morning.
Can you all provide contacts for the vendors below?
Thx
Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 21, 2020 at 7:12:34 AM EDT
To: Gaynor, Pete <pete.gaynor@fema.dhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: White House Coronavirus Task Force Meeting

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/17/2020 7:32:15 PM
To: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS- (b) (6)]
Subject: Fwd: Chloroquine

Thanks colleagues. I would appreciate your input.
Steve

From: Farley, John <John.Farley@fda.hhs.gov>
Date: March 17, 2020 at 6:21:54 PM EDT
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>
Subject: RE: Chloroquine

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/28/2020 9:56:57 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: [EXTERNAL] NYS trial update

Call me when you are free?

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 28, 2020 at 9:44:46 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: [EXTERNAL] NYS trial update

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/15/2020 7:44:36 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: [EXTERNAL] Rapid Immunoassay Kits

Beautifully done.
Very very nice
S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 15, 2020 at 7:36:23 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: [EXTERNAL] Rapid Immunoassay Kits

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/15/2020 7:37:30 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: [EXTERNAL] Rapid Immunoassay Kits

I'll ask my Deputy, Anand Shah to look into it.
Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 15, 2020 at 7:36:23 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: [EXTERNAL] Rapid Immunoassay Kits

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/17/2020 5:43:41 PM
To: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]
Subject: RE: Chloroquine

Much thanks.
Steve

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Date: March 17, 2020 at 5:39:32 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Debi Birx <Deborah.L.Birx@nsc.eop.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>
Subject: RE: Chloroquine

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/20/2020 6:56:09 PM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9d983419fcd-HHS-olx1-cd]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; McGuffee, Tyler A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
Subject: Re: Treatment Document

Deb and Bob,

Let's the 3 of us review. If any of us have concerns, we'll have a call to adjudicate. If we all concur, we'll call it final, clear through WH comms and then coordinate with CDC for distribution. Sound ok?

Steve

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>
Date: March 20, 2020 at 6:45:32 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Lane, Henry C (NIH) <clane@niaid.nih.gov>
Subject: Treatment Document

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/27/2020 8:25:11 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Chinese convalescent plasma pre-print in BMJ

These are interesting and promising early results.

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Date: March 26, 2020 at 4:37:31 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: Chinese convalescent plasma pre-print in BMJ

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/21/2020 6:29:34 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Subject: Re: Hand Sanitizer

Used to be called ATF

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: March 21, 2020 at 6:28:29 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Hand Sanitizer

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/9/2020 12:31:29 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Do we that testing 101

You mean online at coronavirus.gov?
If so, the answer is yes, it is online and was by the deadline.
I have more updated information, as well.
Thanks
S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: March 9, 2020 at 10:54:31 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Do we that testing 101

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/16/2020 2:26:09 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; kac@who.eop.gov
Subject: Fwd: Blood Donation

Kellyanne and Deb,

(b) (5)

. Please let me know how we can help.

Steve

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 16, 2020 at 2:09:01 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Blood Donation

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/13/2020 1:18:54 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Swabs/ Viral Transport Media Tubes

Jeff
Thx. Copying Dr. Birx. There are additional questions.
Steve

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: March 13, 2020 at 12:38:13 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Swabs/ Viral Transport Media Tubes

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/8/2020 9:27:49 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Droegemeier, Kelvin K. EOP/OSTP [REDACTED] (b) (6)@ostp.eop.gov]
CC: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Pottinger, Matthew F. EOP/WHO [REDACTED] (b) (6)@who.eop.gov]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Kratsios, Michael J. EOP/OSTP [REDACTED] (b) (6)@ostp.eop.gov]; Bonner, Maria K. EOP/WHC [REDACTED] (b) (6)@who.eop.gov]; Campana, Alexandra D. EOP/WHC [REDACTED] (b) (6)@who.eop.gov]; Caro Rivera, Juan A. EOP/WHO [REDACTED] (b) (6)@who.eop.gov]; Watson, Ian D. EOP/OSTP [REDACTED] (b) (6)@ostp.eop.gov]; Waterman, Paige E. EOP/OSTP [REDACTED] (b) (6)@ostp.eop.gov]
Subject: Re: Devices for surface testing

Thanks, Joe. Preliminary read but happy to have a conversation.

(b) (5)

[REDACTED] (b) (5). Let us know how we can help further.
Steve

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: March 7, 2020 at 8:20:04 PM EST
To: Droegemeier, Kelvin K. EOP/OSTP <[REDACTED] (b) (6)@ostp.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Redfield, Robert R (CDC) <olx1@cdc.gov>, McGowan, Robert K (CDC) <omc2@cdc.gov>, Pottinger, Matthew F. EOP/WHO [REDACTED] (b) (6)@who.eop.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Kratsios, Michael J. EOP/OSTP [REDACTED] (b) (6)@ostp.eop.gov>, Bonner, Maria K. EOP/WHO [REDACTED] (b) (6)@who.eop.gov>, Campana, Alexandra D. EOP/WHO [REDACTED] (b) (6)@who.eop.gov>, Caro Rivera, Juan A. EOP/WHO [REDACTED] (b) (6)@who.eop.gov>, Watson, Ian D. EOP/OSTP [REDACTED] (b) (6)@ostp.eop.gov>, Waterman, Paige E. EOP/OSTP [REDACTED] (b) (6)@ostp.eop.gov>
Subject: Re: Devices for surface testing

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/27/2020 2:00:09 PM
To: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Joe Grogan [Joseph.J.Grogan@who.eop.gov]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
Subject: Fwd: Chinese convalescent plasma pre-print in BMJ

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Date: March 26, 2020 at 4:37:31 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: Chinese convalescent plasma pre-print in BMJ

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/8/2020 9:13:40 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Droegemeier, Kelvin K. EOP/OSTP [REDACTED] (b) (6)@ostp.eop.gov]
CC: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Pottinger, Matthew F. EOP/WHO [MPottinger@who.eop.gov]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Kratsios, Michael J. EOP/OSTP [REDACTED] (b) (6)@ostp.eop.gov]; Bonner, Maria K. EOP/WHO [REDACTED] (b) (6)@who.eop.gov]; Campana, Alexandra D. EOP/WHO [REDACTED] (b) (6)@who.eop.gov]; Caro Rivera, Juan A. EOP/WHO [REDACTED] (b) (6)@who.eop.gov]; Watson, Ian D. EOP/OSTP [REDACTED] (b) (6)@ostp.eop.gov]; Waterman, Paige E. EOP/OSTP [REDACTED] (b) (6)@ostp.eop.gov]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]
Subject: Re: Devices for surface testing

Very good question. We'll investigate.
Steve

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: March 7, 2020 at 8:20:04 PM EST
To: Droegemeier, Kelvin K. EOP/OSTP <[REDACTED] (b) (6)@ostp.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Redfield, Robert R (CDC) <olx1@cdc.gov>, McGowan, Robert K (CDC) <omc2@cdc.gov>, Pottinger, Matthew F. EOP/WHO [REDACTED] (b) (6)@who.eop.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Kratsios, Michael J. EOP/OSTP [REDACTED] (b) (6)@ostp.eop.gov>, Bonner, Maria K. EOP/WHO [REDACTED] (b) (6)@who.eop.gov>, Campana, Alexandra D. EOP/WHO [REDACTED] (b) (6)@who.eop.gov>, Caro Rivera, Juan A. EOP/WHO [REDACTED] (b) (6)@who.eop.gov>, Watson, Ian D. EOP/OSTP [REDACTED] (b) (6)@ostp.eop.gov>, Waterman, Paige E. EOP/OSTP [REDACTED] (b) (6)@ostp.eop.gov>
Subject: Re: Devices for surface testing

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/11/2020 6:07:36 AM
To: Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Wellstar in GA

(b) (5)

From: Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>
Date: March 10, 2020 at 11:23:23 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Wellstar in GA

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/5/2020 3:12:20 PM
To: McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Operational Check-in

Absolutely
Deb, let me know how you want to proceed

From: McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Date: May 5, 2020 at 3:11:27 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: FW: Operational Check-in

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/2/2020 6:57:57 PM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]
Subject: Fwd: New Understanding of Covid Infection

Interesting, particularly the fecal-oral issues.
Steve

From: John Kennedy <john@johnkennedy.com>
Date: May 2, 2020 at 1:12:20 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: New Understanding of Covid Infection

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/6/2020 10:08:59 AM
To: CMS SV1 (b) (6) cms.hhs.gov]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS- (b) (6)]
Subject: Re: testing

(b) (5)

Steve

From: CMS (b) (6) <(b) (6) cms.hhs.gov>
Date: May 5, 2020 at 3:24:21 PM EDT
To: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Fauci, Anthony S (NIH) <(b) (6) niaid.nih.gov>
Subject: testing

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/4/2020 4:05:40 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Campana, Alexandra D. EOP/WHO [REDACTED] (b) (6)@who.eop.gov]; Williams, Michael B. EOP/WHO [REDACTED] (b) (6)@who.eop.gov]
CC: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
Subject: Re: Have to cancel fda briefings today. My apologies

No worries, Joe.

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: May 4, 2020 at 2:07:33 PM EDT
To: Campana, Alexandra D. EOP/WHO [REDACTED] (b) (6)@who.eop.gov>, Williams, Michael B. EOP/WHO [REDACTED] (b) (6)@who.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Subject: Have to cancel fda briefings today. My apologies

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/6/2020 7:36:32 AM
To: Uehlecke, Nicholas (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd8adca6507d486fb2017138076f4b49-HHS-Nichola]; mrkim tymak.com [mrkim@tymak.com]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; ANDRELH4 [ANDRELH4@dni.gov]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: Time sensitive testing kit information

I'm copying my deputy, Dr. Anand Shah, who can make the connection.
Steve

From: Uehlecke, Nick (HHS/IOS) <Nicholas.Uehlecke@hhs.gov>
Date: May 5, 2020 at 5:06:41 PM EDT
To: mrkim tymak.com <mrkim@tymak.com>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, ANDRELH4 <ANDRELH4@dni.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Time sensitive testing kit information

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/6/2020 7:35:03 AM
To: Short, Marc T. EOP/OVP [Marc.T.Short@ovp.eop.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: Remdesivir Distribution Plan

Kadlec is involved because this is a donation to the USG which goes through BARDA [REDACTED] (b) (5)
[REDACTED] The distribution will not be limited to 7 states. I'm copying Keagan and Anand who have been involved from FDA's perspective.
Steve

From: Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>
Date: May 5, 2020 at 6:14:37 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Remdesivir Distribution Plan

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/6/2020 7:16:51 PM
To: McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: Task Force mtg is now at 5pm tomorrow

4pm is best and more convenient for everyone, I think.
Steve

From: McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Date: May 6, 2020 at 5:59:40 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Subject: FW: Task Force mtg is now at 5pm tomorrow
Importance: High

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/3/2020 1:07:14 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: FW: Remdesivir Allocation

Anand and Keagan,

I just spoke to Dr. Birx who is copied above. [REDACTED] (b) (5)

[REDACTED]
[REDACTED]
[REDACTED]

Thanks
Steve

From: Polowczyk, John P RADM USN JS J4 (USA) <john.p.polowczyk.mil@mail.mil>
Date: May 2, 2020 at 9:19:33 AM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Cc: Kushner, Jared C. EOP/WHO <jck@who.eop.gov>, Pete Gaynor <pete.gaynor@fema.dhs.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>
Subject: FW: Remdesivir Allocation

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/3/2020 9:01:07 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
CC: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]
Subject: RE: New Understanding of Covid Infection

Totally agree. Look forward to it.
Steve

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>
Date: May 2, 2020 at 9:56:49 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: RE: New Understanding of Covid Infection

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/6/2020 7:59:43 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; CMS SV1 (b) (6)@cms.hhs.gov]
CC: Campana, Alexandra D. EOP/WHO (b) (6)@who.eop.gov]; McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
Subject: Re: Operational Check-In

Thanks, Deb. We will appropriately rename the meeting.
Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: May 6, 2020 at 7:58:49 PM EDT
To: Rom, Colin <Colin.Rom@fda.hhs.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, CMS (b) (6) <(b) (6)cms.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Campana, Alexandra D. EOP/WHO (b) (6), McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Subject: Re: Operational Check-In

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/27/2020 2:24:25 PM
To: Butler, Jay C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]; CMS (b) (6) [(b) (6)@cms.hhs.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
CC: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Troye, Olivia (nsc.eop.gov) [Olivia.Troye@nsc.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Beckham, Tammy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8b3c038e4917469dbb5666f0464192b3-HHS-Tammy.B]
Subject: RE: Comprehensive use of COVID tests

Thanks, Jay

From: Butler, Jay C. (CDC/DDID/OD) <jcb3@cdc.gov>
Date: May 27, 2020 at 1:57:58 PM EDT
To: CMS (b) (6) <(b) (6)@cms.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Fauci, Anthony S (NIH) <(b) (6)@niaid.nih.gov>, Troye, Olivia (nsc.eop.gov) <Olivia.Troye@nsc.eop.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>
Subject: RE: Comprehensive use of COVID tests

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/20/2020 3:29:15 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: Fwd: Nucleocapsid Protein Serology Tests vs Spike Protein Serology Tests

FYI
Nice work by Jeff and his team.
Steve

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: May 20, 2020 at 11:41:44 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Nucleocapsid Protein Serology Tests vs Spike Protein Serology Tests

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/27/2020 1:21:46 PM
To: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9d983419fcd-HHS-olx1-cd]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
Subject: Fwd: Bloomberg: Covid Patients Testing Positive After Recovery Aren't Infectious, Study Shows

(b) (5)

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: May 20, 2020 at 10:16:18 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: Bloomberg: Covid Patients Testing Positive After Recovery Aren't Infectious, Study Shows

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/22/2020 12:55:35 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: OWS Tx Update - 21MAY2020

FYI

From: Bugin, Kevin <Kevin.Bugin@fda.hhs.gov>
Date: May 21, 2020 at 8:43:15 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: OWS Tx Update - 21MAY2020

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/9/2020 10:03:35 AM
To: McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: Agenda items for Monday's doctors meeting

I spoke to Bob this morning and I believe that he, Tony and I will be attending any meetings by phone for the next 10-14 days.

Thanks
Steve

From: McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Date: May 9, 2020 at 10:01:30 AM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: Agenda items for Monday's doctors meeting

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/14/2020 8:42:28 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: CDC/FDA Serology Test Document

FYSA

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: May 14, 2020 at 8:39:57 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: CDC/FDA Serology Test Document

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/8/2020 12:47:30 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: Follow up discussion (5/8) 3:00pm Ward Room

Oh ok.

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: May 8, 2020 at 12:46:27 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: Follow up discussion (5/8) 3:00pm Ward Room

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/15/2020 6:01:55 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Did you all just put out an alert on Abbott ID Now

We put out additional information/guidance. Abbott did as well. We alerted the WH

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: May 14, 2020 at 8:22:43 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Did you all just put out an alert on Abbott ID Now

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/9/2020 10:25:49 AM
To: Conley, Sean P. CDR USN WHMO/WHMU [Sean.Conley@whmo.mil]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
CC: Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Jones, James J. EOP/OA (b) (6);@oa.eop.gov]
Subject: Re: HCQ PEP?

(b) (5)

Steve

From: Conley, Sean P. CDR USN WHMO/WHMU <Sean.Conley@whmo.mil>
Date: May 7, 2020 at 7:16:05 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Cc: Lane, Henry C (NIH) <clane@niaid.nih.gov>, Jones, James J. EOP/OA (b) (6);@oa.eop.gov>
Subject: HCQ PEP?

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/8/2020 12:36:26 PM
To: McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: Follow up discussion (5/8) 3:00pm Ward Room

Just saw this. Deb, should I defer the therapeutics review for early next week or this weekend?
Steve

From: McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Date: May 8, 2020 at 9:57:36 AM EDT
To: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Conrad, Patricia L (NIH) <conradpa@niaid.nih.gov>, Knotts, Ashley (CDC) <vqf0@cdc.gov>, Good-Cohn, Meredith (CMS) <Meredith.Good-Cohn@cms.hhs.gov>, Sherman, Jennifer (OS) <Jennifer.Sherman@hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Fauci, Anthony S (NIH) <(b) (6)@niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, (b) (6)@cms.hhs.gov' <(b) (6)@cms.hhs.gov>, Adams, Jerome (OS) <Jerome.Adams@hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Subject: Follow up discussion (5/8) 3:00pm Ward Room

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/14/2020 5:00:28 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Clarification

Ok. I'm on a BARDA call until 6. Let me know what works for you.
S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: May 14, 2020 at 4:51:10 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Clarification

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/8/2020 12:29:21 PM
To: Tyler Ann McGuffee [Tyler.A.McGuffee2@ovp.eop.gov]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Fwd: Follow up discussion (5/8) 3:00pm Ward Room

Tyler Ann,

Deb and I spoke this morning and we are going to have a review of Janet Woodcock's plan for therapeutics development. Deb, can you confirm? I'll ask Keagan to pass along the presentation. Janet will be calling in.

thanks

Steve

From: McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Date: May 8, 2020 at 12:26:20 PM EDT
To: Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Conrad, Patricia L (NIH) <conradpa@niaid.nih.gov>, Knotts, Ashley (CDC) <vqf0@cdc.gov>, Good-Cohn, Meredith (CMS) <Meredith.Good-Cohn@cms.hhs.gov>, Sherman, Jennifer (OS) <Jennifer.Sherman@hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, (b) (6)cms.hhs.gov' <(b) (6)cms.hhs.gov>, Adams, Jerome (OS) <Jerome.Adams@hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Subject: RE: Follow up discussion (5/8) 3:00pm Ward Room

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/14/2020 8:02:45 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) CMS SV1 [(b) (6)@cms.hhs.gov]; Deborah Birx [Deborah.L.Birx@nsc.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9d983419fcd-HHS-olx1-cd]
Subject: RE: Nursing home reopening and testing guidance- draft. Confidential. Deliberative

Seema,
I am also on that teleconference. If it's ok with you, I'll ask Anand to attend.
Steve

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>
Date: May 14, 2020 at 6:35:52 AM EDT
To: CMS (b) (6) <(b) (6)@cms.hhs.gov>, Deborah Birx <Deborah.L.Birx@nsc.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: RE: Nursing home reopening and testing guidance- draft. Confidential. Deliberative

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/14/2020 12:22:47 PM
To: Debi Birx [REDACTED] (b) (6) nsc.eop.gov]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Fwd: COVID diagnostics

Background for our call.
Steve

From: Stevenson, Mark <mark.stevenson@thermofisher.com>
Date: May 14, 2020 at 9:49:10 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COVID diagnostics

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/13/2020 7:58:36 PM
To: Michael, Molly A. EOP/WHO (b) (6)@who.eop.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6)]
Subject: Re: From POTUS

thanks, Molly

From: Michael, Molly A. EOP/WHO (b) (6)@who.eop.gov>
Date: May 13, 2020 at 6:35:37 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: From POTUS

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/8/2020 12:55:38 PM
To: Short, Marc T. EOP/OVP [Marc.T.Short@ovp.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Abbott ID Now Test

Thanks, Marc.
Steve

From: Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>
Date: May 7, 2020 at 7:00:12 PM EDT
To: Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: FW: Abbott ID Now Test

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/27/2020 5:15:17 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: I was excluded from the 3 and 4 pm

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 27, 2020 at 3:23:24 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: I was excluded from the 3 and 4 pm

Sent from my iPhone

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/25/2020 12:48:46 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Fantastic job today.

Thanks

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 24, 2020 at 6:02:59 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fantastic job today.

Sent from my iPhone

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/21/2020 7:59:18 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Serological Test TPs 4.20 CFR_SC V2
Attachments: Serological Test TPs 4.20 CFR_SC V2.docx

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Date: April 20, 2020 at 7:47:47 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: Serological Test TPs 4.20 CFR_SC V2

Here is what Devin and I worked through. He said we are more than ok to make edits

From: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Date: April 20, 2020 at 5:10:55 PM EDT
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Serological Test TPs 4.20 CFR_SC V2

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/23/2020 5:01:17 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) [nelson.l.michael2.civ@mail.mil]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: Re: if possible review in mins not hours

Sounds good

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 23, 2020 at 4:41:38 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>, Fauci, Anthony S (NIH) <(b) (6) niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: if possible review in mins not hours

Yes – we can define it

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: Thursday, April 23, 2020 at 4:36 PM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA)" <nelson.l.michael2.civ@mail.mil>, "Fauci, Anthony S (NIH)" <(b) (6) niaid.nih.gov>, "Redfield, Robert R (CDC)" <olx1@cdc.gov>
Subject: Re: if possible review in mins not hours

(b) (5)

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 23, 2020 at 4:32:54 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>, Fauci, Anthony S (NIH) <(b) (6) niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: if possible review in mins not hours

(b) (5)

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: Thursday, April 23, 2020 at 4:30 PM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>, "Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA)" <nelson.l.michael2.civ@mail.mil>, "Fauci, Anthony S (NIH)" <(b) (6) niaid.nih.gov>, "Redfield, Robert R (CDC)" <olx1@cdc.gov>
Subject: Re: if possible review in mins not hours

Looks good

(b) (5)

?

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>

Date: April 23, 2020 at 2:14:58 PM EDT

To: Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>

Subject: if possible review in mins not hours

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 5/29/2020 12:45:25 PM
To: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Seema Verma [Seema.Verma.OA@cms.hhs.gov]; Hahn, Stephen [REDACTED] (b) (6)
[REDACTED]-Stephen.Hah]
Subject: Posting for testing package Monday am

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/26/2020 2:28:59 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Subject: Re: EUA for diagnostics

Our EUAs are for specific tests and specific lab developers/manufacturers. They require a prescription by a healthcare provider. The indication is for individuals who are 'suspected of COVID19 by their health care provider.' They don't have to be symptomatic. [REDACTED] (b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

Glad to talk further.

Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 26, 2020 at 12:26:30 PM EDT
To: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: EUA for diagnostics

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/1/2020 8:14:28 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: Abbott Lateral Flow

I'd like to discuss this with you.

Thanks

Steve

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Date: April 30, 2020 at 11:35:29 AM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Smith, Brad (CMS) <Brad.Smith@cms.hhs.gov>, Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>
Subject: Abbott Lateral Flow

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/26/2020 8:52:22 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
CC: Kushner, Jared C. EOP/WHO [jck@who.eop.gov]
Subject: Re: Antibody tests

(b) (5)

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 26, 2020 at 7:35:42 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Cc: Kushner, Jared C. EOP/WHO <jck@who.eop.gov>
Subject: Antibody tests

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/1/2020 6:49:02 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
CC: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Williams, Michael B. EOP/WHO (b) (6)@who.eop.gov; DeValliere, Ian C. EOP/WHO (b) (6)@who.eop.gov; Campana, Alexandra D. EOP/WHO (b) (6)@who.eop.gov; McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: two meetings monday

Joe
That's a good plan. Will your office coordinate?
Steve

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: May 1, 2020 at 5:25:58 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Williams, Michael B. EOP/WHO (b) (6)@who.eop.gov, DeValliere, Ian C. EOP/WHO (b) (6)@who.eop.gov, Campana, Alexandra D. EOP/WHO (b) (6)@who.eop.gov, McGuffee, Tyler Ann A. EOP/OVP <Tyler.A.McGuffee2@ovp.eop.gov>
Subject: two meetings monday

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/30/2020 7:44:59 PM
To: O'Brien, Robert C. EOP/WHO (b) (6).@who.eop.gov]
Subject: Re: Vaccines

Hi Ambassador,
I had a call today with the Ambassador today. Could we touch base tomorrow?
Thanks
Steve

From: O'Brien, Robert C. EOP/WHO (b) (6).@who.eop.gov>
Date: April 29, 2020 at 2:32:35 PM EDT
To: BONNE Emmanuel <emmanuel.bonne@elysee.fr>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Vaccines

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/25/2020 12:48:55 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Fantastic job today.

Thanks

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 24, 2020 at 6:02:59 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fantastic job today.

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/25/2020 12:42:11 PM
To: John P RADM USN JS J4 Polowczyk [john.p.polowczyk.mil@mail.mil]; Gaynor, Pete [pete.gaynor@fema.dhs.gov]; Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Kushner, Jared C. EOP/WHO [jck@who.eop.gov]
Subject: FW: MOFCOM new policy on export Medical supplies

I'm sure you all are aware of this good news.
Steve

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 25, 2020 at 10:14:29 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: MOFCOM new policy on export Medical supplies

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/24/2020 8:29:33 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) [nelson.l.michael2.civ@mail.mil]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9d983419fcd-HHS-olx1-cd]
Subject: RE: if possible review in mins not hours

Sounds good.

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>
Date: April 23, 2020 at 10:00:19 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: RE: if possible review in mins not hours

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/30/2020 6:33:40 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS (b) (6)-]
Subject: Fwd: Serology Studies in Germany

Interesting information from Germany

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 30, 2020 at 5:46:27 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Guram, Jeet <Jeet.Guram@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Serology Studies in Germany

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/25/2020 3:30:44 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: Fwd: HESI Testing Proposal

My apologies. I am going through my inbox now.
Wanted you to be aware.
Steve

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 24, 2020 at 1:34:10 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: HESI Testing Proposal

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 5/1/2020 8:47:19 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Testing Centers

Thought this might be of interest to you. Anand Shah from my office is following up with Dr. Brennan.
Steve

From: Merlo, Larry J. <Larry.Merlo@CVSHealth.com>
Date: April 30, 2020 at 9:53:26 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Brennan, Troyen A. <Troyen.Brennan@CVSHealth.com>
Subject: Testing Centers

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/23/2020 9:56:45 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Call with Dr. Hahn tomorrow

Ok thanks

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 23, 2020 at 9:53:58 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Call with Dr. Hahn tomorrow

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/23/2020 9:34:49 AM
To: Sheila Peel [speel@hivresearch.org]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: Re: [EXTERNAL] RUO and EUA

Copying Jeff Shuren the Director of CDRH

From: Sheila Peel <speel@hivresearch.org>
Date: April 22, 2020 at 10:48:22 AM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: [EXTERNAL] RUO and EUA

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/21/2020 3:42:49 PM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: RE: Viral Clades Brufsky 42020 Accepted Final.pdf

Thanks, Tony. I'll be sending another article that is to be submitted to Nature from the same US authors.

(b) (5)
Steve

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>
Date: April 21, 2020 at 3:41:13 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: RE: Viral Clades Brufsky 42020 Accepted Final.pdf

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/23/2020 5:37:35 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6)]
Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
Subject: Re: Serology Test Calculator

We've approved 4 EUAs and (b) (6)

Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 21, 2020 at 4:06:03 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>
Subject: Re: Serology Test Calculator

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/21/2020 8:25:52 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]; Short, Marc T. EOP/OVP [Marc.T.Short@ovp.eop.gov]
CC: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Billet, Courtney R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=04ddfe30e6154dd5ab720f23eb6070df-HHS-billetec]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Myles, Renate H (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=04a3e5f0ac384bd6b70bd9cdee9082f2-HHS-mylesr-]
Subject: Re: FYI - "Coronavirus Disease 2019 (COVID-19) Treatment Guidelines"

Thanks, Tony.
Steve

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>
Date: April 20, 2020 at 11:54:01 AM EDT
To: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>, Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Billet, Courtney R (NIH) <billetec@niaid.nih.gov>, Hall, Bill (OS) <bill.hall@hhs.gov>, O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lane, Henry C (NIH) <clane@niaid.nih.gov>, Myles, Renate H (NIH) <mylesr@mail.nih.gov>
Subject: FYI - "Coronavirus Disease 2019 (COVID-19) Treatment Guidelines"

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/27/2020 5:15:25 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: I was excluded from the 3 and 4 pm

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 27, 2020 at 3:23:24 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: I was excluded from the 3 and 4 pm

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/27/2020 9:52:32 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS- (b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Tyler Ann McGuffee [Tyler.A.McGuffee2@ovp.eop.gov]
Subject: Re: Testing Strategy

I sent my comments at 8:30 am and then also sent to Tyler. Received?

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 27, 2020 at 9:50:35 AM EDT
To: Fauci, Anthony S (NIH) <(b) (6)@niaid.nih.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: Testing Strategy

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/21/2020 3:23:18 PM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9d983419fcd-HHS-olx1-cd]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
Subject: Fwd: Serology Test Calculator

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 20, 2020 at 6:26:14 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Serology Test Calculator

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/27/2020 8:29:13 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: Re: Testing Strategy
Attachments: 20200422 Testing Strategy SUNDAY2 (redline).docx

My comments. Sorry, I used my iPad so its a little messy.

(b) (5)

Thanks
Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 27, 2020 at 7:53:40 AM EDT
To: Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: FW: Testing Strategy

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/21/2020 7:59:24 AM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: Serological Test TPs 4.20 CFR_SC V2

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Date: April 20, 2020 at 7:47:47 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: Serological Test TPs 4.20 CFR_SC V2

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/23/2020 5:01:26 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) [nelson.l.michael2.civ@mail.mil]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: Re: if possible review in mins not hours

Sounds good

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 23, 2020 at 4:41:38 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: if possible review in mins not hours

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/29/2020 8:50:31 PM
To: Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]
Subject: Re: Question

(b) (5)

From: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Date: April 29, 2020 at 5:57:30 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Question

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/23/2020 4:35:47 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) [nelson.l.michael2.civ@mail.mil]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]
Subject: Re: if possible review in mins not hours

(b) (5)

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 23, 2020 at 4:32:54 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: if possible review in mins not hours

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/21/2020 2:29:35 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: Fwd: POTUS comment for today

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: April 21, 2020 at 2:29:14 PM EDT
To: Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: POTUS comment for today

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/23/2020 4:30:38 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) [nelson.l.michael2.civ@mail.mil]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: Re: if possible review in mins not hours

Looks good

(b) (5)

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 23, 2020 at 2:14:58 PM EDT
To: Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <nelson.l.michael2.civ@mail.mil>, Fauci, Anthony S (NIH) <(b) (6)niaid.nih.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: if possible review in mins not hours

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/29/2020 5:27:42 PM
To: Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]
Subject: Re: Question

(b) (5)

From: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Date: April 29, 2020 at 5:11:54 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Question

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/21/2020 1:51:41 PM
To: Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: Follow Up - White House Correspondence

Katie,

They should be told to submit an application to us which we are happy to review. On the FDA website they can go to our CTAP inbox and send us a message. We'll follow up when they do.

Steve

From: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Date: April 21, 2020 at 11:50:54 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: Follow Up - White House Correspondence

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/21/2020 1:40:09 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Subject: RE: FYI [REDACTED] (b) (5)

Yes and I called Mark Meadows and left him a message.

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: April 21, 2020 at 1:33:38 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: FYI: [REDACTED] (b) (5)

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/19/2020 1:50:48 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
Subject: Re: Germany antibody testing

(b) (4).

S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 19, 2020 at 1:46:29 PM EDT
To: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Germany antibody testing

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/20/2020 9:04:38 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; CMS SV1 (b) (6) cms.hhs.gov]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
Subject: Re: COVID testing and CLIA

+ Dr. Shah

Deb,

That is exactly what was raised as an issue. Anand, was going to connect CDRH and CMS.

Thanks

Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 20, 2020 at 8:26:58 AM EDT
To: CMS (b) (6) <(b) (6) cms.hhs.gov>
Cc: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: COVID testing and CLIA

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/21/2020 12:25:06 PM
To: Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]
Subject: Re: Follow Up - White House Correspondence

Will do. Do you know who received the April 8 outreach?
Steve

From: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Date: April 21, 2020 at 11:50:54 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: Follow Up - White House Correspondence

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/20/2020 7:52:41 AM
To: Ford, Robert B [Robert.Ford@abbott.com]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Deborah Birx (deborah.l.birx@nsc.eop.gov) [deborah.l.birx@nsc.eop.gov]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]; Haddad, Carla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8627be6986b64424883e696551c54187-HHS-Carla.H]
Subject: Re: Abbott's Covid Data

Thanks, Robert

From: Ford, Robert B <Robert.Ford@abbott.com>
Date: April 19, 2020 at 6:03:59 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Deborah Birx (deborah.l.birx@nsc.eop.gov) <deborah.l.birx@nsc.eop.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Haddad, Carla (OS) <Carla.Haddad@hhs.gov>
Subject: Re: Abbott's Covid Data

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/21/2020 12:24:17 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
Subject: FW: FYI: Information request to ANSM on CV risks from chloroquine/hydroxychloroquine
Importance: High

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: April 21, 2020 at 12:15:50 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: FW: FYI: Information request to ANSM on CV risks from chloroquine/hydroxychloroquine
Importance: High

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/28/2020 7:53:00 AM
To: Watts, Mary Lee [mwatts@asmusa.org]; 'Birx, Deborah L. EOP/NSC' [Deborah.L.Birx@nsc.eop.gov]
CC: Segal, Allen [asegal@asmusa.org]; Bertuzzi, Stefano [sbertuzzi@asmusa.org]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Subject: RE: Thank you

I'd be very happy to meet with Dr. Patel while we are at Mayo, schedule permitting. Do you have contact information? I really appreciate your reaching out. I'm copying Janice.
Steve

From: Watts, Mary Lee <mwatts@asmusa.org>
Date: April 27, 2020 at 5:06:27 PM EDT
To: 'Birx, Deborah L. EOP/NSC' <Deborah.L.Birx@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Segal, Allen <asegal@asmusa.org>, Bertuzzi, Stefano <sbertuzzi@asmusa.org>
Subject: RE: Thank you

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/28/2020 6:33:39 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: You ok?

I'm ok. You?
May I call you to touch base when I land?

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 28, 2020 at 6:29:21 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: You ok?

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/28/2020 7:50:52 AM
To: CMS SV1 (b) (6) cms.hhs.gov; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9d983419fcd-HHS-olx1-cd]
Subject: Re: Antibody test

It would be great to have additional discussion about these issues. I'm sure we are all getting a lot of questions.
Steve

From: CMS (b) (6) <(b) (6) cms.hhs.gov>
Date: April 27, 2020 at 1:05:45 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Fauci, Anthony S (NIH) <(b) (6) niaid.nih.gov>, Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Antibody test

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/26/2020 6:34:17 PM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: EUA for diagnostics

Glad to talk. I have a couple of ideas

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: April 26, 2020 at 4:30:28 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: EUA for diagnostics

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/23/2020 7:22:14 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]
Subject: FW: Call with Dr. Hahn tomorrow

Thoughts?

From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Date: April 22, 2020 at 8:59:07 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: FW: Call with Dr. Hahn tomorrow

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/28/2020 7:45:30 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
CC: Redd, Stephen C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb0e6496f1af42ce9f8e0d4f92fae009-HHS-scr1-cd]
Subject: Re: Flagging NIH Media Product for Release Tomorrow

this is great news. Bruce Tromberg is terrific.
Steve

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)niaid.nih.gov>
Date: April 27, 2020 at 5:48:56 PM EDT
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Cc: Redd, Stephen C (CDC) <scr1@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Flagging NIH Media Product for Release Tomorrow

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/20/2020 7:09:31 AM
To: CMS SV1 (b) (6) cms.hhs.gov; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: COVID testing and CLIA

this is terrific, Seema. Well done. I am sharing with my team.

From: CMS (b) (6) <(b) (6) cms.hhs.gov>
Date: April 19, 2020 at 10:34:29 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Subject: COVID testing and CLIA

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/27/2020 11:49:11 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS (b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]
Subject: Re: Testing Strategy

I'm pulling in Seema to expand the conversation.

(b) (5)

Thanks
Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 27, 2020 at 7:53:40 AM EDT
To: Fauci, Anthony S (NIH) <(b) (6) niaid.nih.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: FW: Testing Strategy

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/20/2020 1:54:53 PM
To: Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]
Subject: Re: clinical trials

Let's talk

From: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Date: April 20, 2020 at 1:16:54 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: clinical trials

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/19/2020 10:09:43 AM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: [EXTERNAL] FW: CBER Update

We can certainly support that. Will WH IGA reach out to the individuals? Will WH organize the podium event otherwise?

Steve

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: April 18, 2020 at 6:50:33 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: [EXTERNAL] FW: CBER Update

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/17/2020 10:44:45 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]
CC: Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Rinat, Ory S. EOP/WHO [Ory.S.Rinat@who.eop.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: Charts needed by 12pm

Understood. We're working on it.
Steve

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 17, 2020 at 9:59:46 AM EDT
To: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Cc: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Rinat, Ory S. EOP/WHO <Ory.S.Rinat@who.eop.gov>
Subject: Re: Charts needed by 12pm

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/21/2020 9:13:29 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Follow up from yesterday's therapeutics discussion

Thanks

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 21, 2020 at 9:12:35 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Follow up from yesterday's therapeutics discussion

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/20/2020 12:50:09 PM
To: Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]
CC: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Subject: Re: Presse today

Yes, for sure. Expected timing?

From: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Date: April 20, 2020 at 12:36:37 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Subject: Presse today

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/27/2020 11:37:39 AM
To: Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]
Subject: Re: Testing

Yes, only those tests authorized by FDA.

From: Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>
Date: April 27, 2020 at 8:58:37 AM EDT
To: Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: Testing

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/26/2020 2:48:59 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: HESI Testing Proposal

Thanks

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 25, 2020 at 6:04:55 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: HESI Testing Proposal

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/27/2020 11:32:41 AM
To: Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]
Subject: Re: Testing Strategy

Thanks

From: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Date: April 27, 2020 at 10:39:39 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Testing Strategy

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/27/2020 10:22:19 AM
To: Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]
Subject: Re: Testing Strategy

Hi Katie,
Our logo can be used. [REDACTED] (b) (5)?
Steve

From: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Date: April 27, 2020 at 8:25:21 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: Testing Strategy

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/18/2020 6:20:07 PM
To: Joe Grogan [Joseph.J.Grogan@who.eop.gov]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: FW: [EXTERNAL] FW: CBER Update

Joe,
It would be great if we could amplify the message significantly.
The names of donors are below.
Thanks
Steve

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Date: April 18, 2020 at 5:51:32 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: [EXTERNAL] FW: CBER Update

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/27/2020 9:53:33 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS (b) (6) -]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]
Subject: Re: Testing Strategy

My edits are within the document that was attached . If you need me to send again, please let me know

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 27, 2020 at 9:50:35 AM EDT
To: Fauci, Anthony S (NIH) <(b) (6)@niaid.nih.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>
Subject: Re: Testing Strategy